IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: *All Wave 5 cases listed in Exhibit A to Defendants' motion*	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

The Plaintiffs respectfully request that this Court deny Defendants' motion that seeks to limit Dr. Bruce Rosenzweig's general opinions for the Wave 5 cases.

INTRODUCTION

Dr. Rosenzweig's opinions have been vetted as much as any expert's in the various MDLs. This Court has consistently found him well qualified to testify on a wide variety of topics. This Court has written, in various *Daubert* orders, that "Dr. Rosenzweig has demonstrated extensive knowledge of and experience with the process of polypropylene mesh degradation in the body"; that "[a]lthough Dr. Rosenzweig has never designed vaginal mesh devices, he has considerable familiarity with their structure and use"; that "Dr. Rosenzweig received thorough training on the implantation of sling products in pelvic repair"; and that "although Dr. Rosenzweig is not a toxicologist, he stated that he regularly encounters cytotoxicity in his practice, including in women who have polypropylene mesh implants." *Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at **5-6 (S.D. W. Va. May 5, 2015); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 707 (S.D. W. Va. 2014).

As a result, this Court "has considered Dr. Rosenzweig as a general causation expert [several] times in the past, and on each occasion [the Court has] admitted his general causation testimony on the properties of polypropylene mesh." *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 565 (S.D. W. Va. 2014), *as amended* Oct. 29, 2014.

Dr. Rosenzweig is a pelvic-floor surgeon based in Chicago. Defendants have described Dr. Rosenzweig as a "[v]ery skilled pelvic floor surgeon,"[1] and Ethicon even invited Dr. Rosenzweig for special training in Belgium on how to implant the TVT-O device. (Rosenzweig General Wave 5 TVT Report ("TVT Report"), attached as Exhibit A, at 2). Dr. Rosenzweig is an assistant professor of Obstetrics and Gynecology at Rush University Medical Center. Previously, he had fellowships at the State University of New York at Syracuse and at UCLA. He started a urogynecology program at the University of Illinois-Chicago, and he has performed more than one thousand surgeries in the pelvic floor, including more than 300 surgeries to address complications associated with synthetic mesh products. Dr. Rosenzweig has also published numerous articles and given numerous lectures on the treatments of urinary incontinence and pelvic organ prolapse. (*Id.* at 1-2).

Ethicon's attacks on Dr. Rosenzweig's opinions are, for the most part, adoptions of prior wave arguments. Ethicon's new arguments should be rejected for the reasons discussed below. Dr. Rosenzweig's opinions have been properly disclosed; his opinions about non-mesh alternatives are relevant; and Dr. Rosenzweig is well qualified to give opinions about Ethicon's testing—or at the very least, to opine as to whether additional testing was needed.

[1] Ethicon surgeon database, attached to Wave 1 response, Dkt. No. 2163-1, at Line 90.

LEGAL STANDARDS

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). This aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

ARGUMENT

The Court should reject Ethicon's arguments for exclusion, as described below. The issues are addressed in the order presented by Ethicon.

I. The Court should deny Ethicon's first request for relief, which cites no rule, order, or other authority for limiting Dr. Rosenzweig's reliance on his prior expert reports and testimony.

Ethicon's first argument is difficult to address because it cites no rule, court order, or edict from case law that Dr. Rosenzweig supposedly has violated. Plaintiffs are also confused as to why Defendants are only now raising the issue that is being raised.

Throughout the Ethicon waves, Dr. Rosenzweig has referred to prior expert reports as his general report. For Wave 5, however, Dr. Rosenzweig has submitted a series of updated, device-specific reports for six Ethicon devices. In addition, as noted in Ethicon's motion, he submitted a handful of prior reports on which he continues to rely, and he made statements generally adopting his prior opinions, as he has done in the past. (Def. Memo at 2-3). It makes little sense that Ethicon would only now complain about Dr. Rosenzweig's adoption of prior reports, after he has clarified his opinions with additional reports.

Again, Ethicon cites no rule or Court order that Dr. Rosenzweig has supposedly violated. He has created new reports specifically for Wave 5, so those reports clearly reveal the opinions he intends to give at trial. But in this unique litigation, Dr. Rosenzweig has already given his opinions dozens of times in various ways—through prior reports, through deposition testimony, and through trial testimony. If he has revealed an opinion—or the rationale to support an opinion—in a prior report or in prior testimony, then the opinion (or rationale) should not be a surprise to Ethicon. The statements incorporating prior opinions and testimony are not intended to confuse anyone. They are simply intended to clarify that Dr. Rosenzweig continues to hold the opinions he has reiterated dozens of times, all of which Ethicon has repeatedly been made aware, without the need for an absurdly long report reiterating all of Dr. Rosenzweig's prior reports and testimony.

II. As this Court has recognized, relevance is a highly case-specific issue. The Court should not issue a blanket exclusion of testimony about non-mesh alternatives when such alternatives may be relevant to design defect and negligence issues in a particular case.

The Court previously rejected Ethicon's next argument during Ethicon Wave 1, and the Court should not backtrack from its sound analysis. The issue is whether Dr. Rosenzweig's opinions regarding the safety of non-mesh procedures should be universally declared as

irrelevant to all trials in Wave 5—regardless of the state law that applies, and regardless of the evidence and arguments in a particular case. When faced with this issue previously, the Court wrote:

> *First*, Ethicon argues that Dr. Rosenzweig should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Ethicon does not challenge Dr. Rosenzweig's qualifications or the reliability of this expert testimony; instead, Ethicon challenges the relevance of this expert testimony. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I RESERVE ruling until trial.

In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., No. 2327, 2016 WL 4500765, at *3 (S.D. W. Va. Aug. 26, 2016). The Court should issue the same ruling in Wave 5.

A. <u>As recently held in the Northern District of Illinois, evidence of non-mesh alternatives is relevant to assessing the utility of Ethicon's products, and to counter Ethicon's assertions that its products are the "gold standard" for treating SUI.</u>

In Dr. Rosenzweig's reports, he discusses the safety and efficacy of the Burch colposuspension—his own preferred treatment for stress urinary incontinence ("SUI")—and also native tissue repair using pubovaginal slings or autologous facial slings. (*See, e.g.*, TVT Report, Ex. A, at pp. 7-10). In his reports, Dr. Rosenzweig opines that the debilitating complications caused by the TVT line of products outweigh the benefits of those devices. (*See id.* at 92-96). He further asserts that "[t]his is especially true given that traditional surgeries like the Burch and pubovaginal slings are not associated with the frequency or extent of these life changing complications." (*Id.* at 93).

This Court did exclude some evidence of alternative procedures in the *Mullins* consolidation, but that order was directed to a specific issue of West Virginia law—i.e., what could constitute a safer alternative design. Given that not all states even require evidence of a

safer alternative design, the Court's ruling should not apply to all circumstances. A recent ruling from the Northern District of Illinois provides an example.

In *Herrera-Nevarez*, a remanded case in the Northern District of Illinois, the plaintiff argued that this Court's order in *Mullins* did not control as to whether Dr. Rosenzweig's opinions were relevant. In *Mullins*, this Court applied West Virginia law and held that "evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." *Mullins v. Johnson & Johnson*, No. 2:12-CV-02952, 2017 WL 711766, at *2 (S.D. W. Va. Feb. 23, 2017). The court also held that polypropylene sutures do not constitute a "product," such that they could serve as an alternative design. *Id.* at **2-3. The court had previously determined that West Virginia law required evidence of a safer alternative design to make a prima facie case for strict liability/defective design. Thus, the question as to the Burch procedure and pubovaginal slings was whether those alternatives could qualify as safer alternative designs to meet that prima facie requirement. *See id.* By contrast, the issue raised by Ethicon in its Wave 5 motion is whether such testimony is **relevant**.

Under Illinois law, as in many states, one consideration in determining whether a product is unreasonably dangerous—applying the risk-utility test—is "[t]he usefulness and desirability of the product—its utility to the user and to the public as a whole." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 260–61 (Ill. 2007). Thus, the *Herrera-Nevarez* plaintiff argued that the availability of non-mesh alternatives bore directly on that inquiry—i.e., the product's utility to the user and to the public as a whole. The plaintiff further argued that this testimony was relevant to the question of negligence, under Illinois law. As in most states, the negligence issue under Illinois law is whether the manufacturer deviated from what a reasonable manufacturer would have done. *See Baltus v. Weaver Div. of Kidde & Co.*, 557 N.E.2d 580, 585–86 (Ill. App.

Ct. 1990). The *Herrera-Nevarez* plaintiff further argued that in assessing whether Ethicon's conduct was reasonable, the jury needed to know whether Ethicon was bringing its mesh product onto a market that had no other options for the treatment of SUI, or whether there were already safe and effective treatments on the market.

Finally, the *Herrera-Nevarez* plaintiff asserted that Dr. Rosenzweig's testimony was relevant because Ethicon would claim that its TVT products represent the safest available treatment for SUI. In fact, Ethicon's experts regularly assert that the TVT products are the "gold standard" for the treatment of SUI. Such assertions would put into issue the question of whether the TVT products are, in fact, the safest and most effective treatment for SUI.

The court agreed and permitted Dr. Rosenzweig to opine about non-mesh alternatives to Ethicon's products. The court wrote that "the availability of other safe and effective procedures to treat the same condition is relevant and admissible, as plaintiffs contend, to show the utility of the defendants' product (factor 1)—a point not addressed in the other cases upon which defendants rely." *Herrera-Nevarez v. Ethicon, Inc.*, No. 12 C 2404, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017).[2] The court further agreed with the plaintiff "that this evidence is admissible to rebut defendants' contention that the TVT-O and similar products are the 'gold standard' for treating SUI." *Id.*

That reasoning explains why it would be inappropriate to issue the blanket exclusion sought by Ethicon. Without examining the particular state law at issue, and without examining the contentions made by Ethicon in a particular case, no court should exclude Dr. Rosenzweig's testimony on these points.

[2] The court's analysis was in reference to Dr. Daniel Elliott, but as the court wrote in addressing Dr. Rosenzweig's testimony immediately thereafter, the issue is exactly the same regardless of the expert involved.

Under Rule 401, the standard for relevance is not high. To be relevant, evidence must have "any tendency to make a fact more or less probable than it would be without the evidence," and the fact must be "of consequence in determining the action." Fed. R. Evid. 401(a)-(b). In the Wave 5 cases, Dr. Rosenzweig will explain that the Burch procedure and pubovaginal slings would have been safer than implanting mesh products, while being equally as effective. (*See, e.g.*, TVT Report at 92-96). As discussed in *Herrera-Nevarez*, such opinions are likely relevant, under a particular state's law, to whether Ethicon's mesh products are unreasonably dangerous, to whether Ethicon was negligent in designing them, and to rebut assertions by Ethicon that its products are the safest and most effective treatments for SUI.

B. Even if the Court excludes testimony about alternative procedures that do not utilize products, such exclusion should not apply to native tissue repair.

Arguing in the alternative, even if the Court concludes that an alternative treatment method must involve a "product" to be relevant, the Court should allow testimony about pubovaginal slings/native tissue repair.

While this Court in *Mullins* rejected the argument that polypropylene sutures in and of themselves could constitute a "product," pubovaginal slings—and other forms of native tissue repair—involve a substantial amount of material **in addition to** the polypropylene sutures that are used to attach the sling. The Court's *Mullins* order did not address this category of product.

Dr. Rosenzweig's TVT report explains pubovaginal slings as follows:

> The procedure involves placing a band of autologous, allograft, xenograft or synthetic material directly under the bladder neck (i.e., proximal urethra) or mid-urethra, which acts as physical support to prevent bladder neck and urethral descent during physical activity. This is brought up through the rectus fascia. The sling also may augment the resting urethral closure pressure with increases in intra-abdominal pressure.

(Rosenzweig TVT Report at 9). Thus, there is substantial additional material involved in a pubovaginal sling, in addition to whatever is used to hold it in place (which may or may not be a polypropylene suture).

Generally, pubovaginal slings use tissue from a human or animal cadaver to create the sling that is used to treat SUI. For instance, one company that produces such products is Coloplast Corp. In describing its product on its website, Coloplast writes:

> **Product description:** Axis dermis has omnidirectional fibers that give it consistent high tensile strength, and the network of collagen bundles interconnecting in every direction make implantation and ingrowth uniform. Axis is extracted only in large pieces from the lower back and the back of upper leg. This gives Axis consistency in quality and structure.

Coloplast: Axis, https://www.coloplast.us/Axis-en-us.aspx#section=product-description_3 (last visited July 31, 2017). As this example describes, pubovaginal slings such as allografts are alternative products to treat stress urinary incontinence, using natural material instead of synthetic polypropylene. They involve much more than sutures.

A pharmaceutical case from this Court held that a jury should decide whether the substitution of natural material for synthetic material constitutes an alternative design. *See Keffer v. Wyeth*, 791 F. Supp. 2d 539, 548-50 (S.D. W. Va. 2011). In *Keffer*, the issue involved a hormonal replacement therapy drug. *Id.* at 541. The plaintiffs argued that the drug was dangerous because of the synthetic progestin in the drug, and asserted that natural material—oral micronized progesterone—would have been a safer ingredient to use in the drug. *Id.* at 548. The defense argued that the use of a natural material created a different product altogether, and therefore could not be held up as a "safer alternative design." But the court held that that was an issue for the jury to decide. *Id.* at 549.

The same reasoning should apply here. The jury should decide whether a product made primarily from native tissue can serve as a safer alternative to mesh products.

III. Dr. Rosenzweig should be permitted to testify about mesh-based safer alternative designs such as Ultrapro.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section I of Dkt. No. 2931.

IV. Dr. Rosenzweig should be permitted to criticize the cut of the TVT mesh.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section II of Dkt. No. 2931.

V. Dr. Rosenzweig should be permitted to give his warnings opinions.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section III of Dkt. No. 2931.

VI. Dr. Rosenzweig should again be permitted to testify about degradation and other mesh properties, including the cytotoxicity of the mesh.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section IV of Dkt. No. 2931.

VII. Dr. Rosenzweig is qualified by knowledge and experience to opine about product testing, and he should at least be able to opine about the <u>need</u> for testing.

In Section VII, Defendants discuss three topics—opinions about Ethicon's training, adverse event reports ("AERs"), and testing. As to AERs, Dr. Rosenzweig is not seeking to opine about the quality of Ethicon's adverse-event reporting. But the Court should not expand the scope of any rulings regarding adverse events, such that Dr. Rosenzweig would be unable to even mention AERs. At times, he will rely on particular adverse event reports as evidence to support his opinions, as this Court has permitted in the past. *See Mathison v. Boston Sci. Corp.*,

No. 2:13-CV-05851, 2015 WL 2124991, at *20 (S.D. W. Va. May 6, 2015) (denying motion to exclude IFU opinions that commented, *inter alia*, on adverse events not listed in the IFU).

Plaintiffs recognize that this Court has previously excluded Dr. Rosenzweig's opinions as to testing, and they are not seeking reconsideration of that decision at this time. Plaintiff do respectfully request that this Court reconsider its prior ruling that Dr. Rosenzweig is not qualified to opine about Ethicon's testing. Dr. Rosenzweig's opinions about the inadequacy of Ethicon's testing are the product of his expertise about the agents in the female vaginal area. As one example, Dr. Rosenzweig opines that Ethicon should have conducted testing to determine whether the polypropylene degrades. (Rosenzweig TVT Report, Ex. A, at 19). This opinion is a natural corollary to an opinion Dr. Rosenzweig has been permitted to give, that the mesh degrades in vivo. *See Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *5 (S.D. W. Va. May 5, 2015).

Dr. Rosenzweig is not merely relying on his clinical experience in opining about Ethicon's testing (or lack thereof). Rather, he also has substantial experience with testing medical devices to be used in the pelvic region, including the following:

- Dr. Rosenzweig was involved in the development of an Amnio-infusion catheter, and he helped to develop a randomized controlled trial ("RCT") to test infusion into the uterus, as compared with placing a sham single catheter.
- He worked with EMPI on testing the Innova electrical simulator designed to treat SUI, and he helped to design an RCT to test using a sham similar as compared to an active simulator.

- He was an investigator for a study for Lea Shield and Fem cap, both cervical cap contraceptives. The study was designed to choose the appropriate size to avoid pregnancy while also gaining FDA approval as over-the-counter drugs.

(Rosenzweig Affidavit, attached as Exhibit B, at ¶¶ 4-6).

Based on this experience, the Court should conclude that Dr. Rosenzweig is qualified to opine about product testing. Alternatively, even if the Court still believes that Dr. Rosenzweig is unqualified to opine as to the **adequacy** of Ethicon's testing, Dr. Rosenzweig has the experience and expertise to opine about whether testing to evaluate certain potential problems was necessary **at all**, based on the available information. Therefore, this Court should reject the request to issue a blanket exclusion of all opinions related to testing.

VIII. Dr. Rosenzweig should be permitted to give his opinions about the effect of the TVT-Abbrevo product's shorter length.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section VI of Dkt. No. 2931.

IX. Dr. Rosenzweig will not opine about Defendants' marketing practices.

The Defendants' ninth issue is uncontested. The Court has previously excluded Dr. Rosenzweig from opining about Defendants' marketing practices, and Plaintiffs are not seeking reconsideration of that ruling at this time.

X. Dr. Rosenzweig should be permitted to give his opinions about the Material Safety Data Sheet for polypropylene.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section VIII of Dkt. No. 2931.

XI. Dr. Rosenzweig is a case-specific expert for several Prolift cases, and his opinions are disclosed. Regardless, any disclosure issues should be dealt with at trial.

While Dr. Rosenzweig is not serving as a general expert with regard to the Prolift device, he has been designated as a specific expert in certain cases in which the plaintiff has received a Prolift device. Therefore, if Defendants' motion is seeking exclusion of all opinions regarding the Prolift device, then it goes way too far and should be rejected.

Dr. Rosenzweig is both a general and a case-specific expert. He is serving as a case-specific expert in some cases in which the plaintiff has received a Prolift device. Those opinions are disclosed in Dr. Rosenzweig's case-specific reports. In addition, there are some cases where a plaintiff has received more than one device, and Dr. Rosenzweig is a general expert as to the other device. And, where Dr. Rosenzweig has relied on general information about the Prolift device as support for his case-specific opinions, he has revealed those opinions in his case-specific reports, citing to the general report of another expert. For instance, in his report for the case involving Shelby Anders, Dr. Rosenzweig writes that he has "reviewed, relied upon, and independently verified the MDL Prolift Expert Report of Dr. Daniel Elliott." (Rosenzweig Anders Report, attached as Exhibit C, at p. 3).

Because Dr. Rosenzweig has disclosed opinions that relate to Prolift in several individual cases, this issue is ill-suited for a general motion. The sole basis for Defendants' motion is the disclosure rules. This Court should reserve ruling on the issue, and each trial court should determine on a case-by-case basis whether any particular opinion was properly disclosed.

A related point is that courts do have the authority to permit opinions that were not disclosed in a report. *See S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 597 (4th Cir. 2003) (describing factors to consider in determining whether or not to allow evidence not disclosed in an expert report). Dr. Rosenzweig does not intend to give any

undisclosed opinions, but this authority is further reason that such issues should be decided on a case-by-case basis, and not in a general motion.

For these reasons, the Defendants' argument for exclusion of Prolift opinions should be denied. Any allegations that Dr. Rosenzweig is attempting to give an undisclosed opinion should be taken up at trial.

XII. Other opinions

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section X of Dkt. No. 2931.

CONCLUSION

The Court should deny Ethicon's motion, except as to the issues conceded above.

Dated: August 29, 2017

Respectfully submitted,

/s/Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on August 29, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Thomas P. Cartmell
Attorney for Plaintiffs

INDEX OF EXHIBITS

Exhibit A: Bruce Rosenzweig General Wave 5 TVT Report

Exhibit B: Bruce Rosenzweig Affidavit

Exhibit C: Bruce Rosenzweig Anders Case-Specific Report

Case 2:12-md-02327 Document 4550-1 Filed 08/29/17 Page 1 of 101 PageID #: 149550

Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327**
THIS DOCUMENT RELATES TO	**JOSEPH R. GOODWIN**
WAVE 5 CASES	**U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF BRUCE ROSENZWEIG, M.D.

I. QUALIFICATIONS.

I am currently an Assistant Professor of Obstetrics and Gynecology at Rush University Medical Center in Chicago, Illinois. I received my MD degree in 1984 from the University of Michigan in Ann Arbor, Michigan. Following graduation from medical school, I completed an Obstetrics and Gynecology Residency at Michael Reese Hospital in Chicago. In 1988, I attended a one year pelvic surgery fellowship at State University of New York in Syracuse, New York. Following that fellowship, I attended a two year Urogynecology and Urodynamics fellowship at UCLA Harbor General Hospital in Torrance, California. After graduating from the Urogynecology fellowship, I became a faculty member at the University of Illinois in Chicago. I started a Urogynecology program at the University of Illinois and also was the residency program director. In 1998, I went into private practice, and subsequently established a private practice at Rush University Medical Center. I have also worked at John H. Stroger Hospital here in Chicago from May 2003 until November 2010 and Weiss Memorial Hospital as Associate Chair of Gynecology from February 2011 until

July 2012. I have published numerous articles and given numerous lectures on the topics of pelvic organ prolapse, urinary incontinence and repair of pelvic organ prolapse.

Throughout my career, I have performed over a thousand pelvic floor surgical procedures, including abdominal sacrocolpopexy, uterosacral suspensions, sacrospinous ligament fixations, native tissue repairs, biological graft repairs and synthetic mesh repairs. I have also used numerous synthetic pelvic mesh products, including Ethicon's TVT, TVTbturator, and Prolift. In addition, I have performed over 300 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices. I have also treated approximately 800 additional patients with mesh non-surgically. I was invited by Ethicon and attended both its Gynecare Prolift Training Seminar and TVT Obturator Seminar in Belgium. In addition, I was invited and attended a Bard Avaulta training seminar in the past.

A copy of my CV and Fee Schedule is attached as Exhibit "A" and a copy of my testimony for the last four years is attached as Exhibit "B". The documents I relied on for this report are contained in Exhibit "C" as well as those documents cited throughout this Report.

II. SUMMARY OF OPINIONS.

In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Ethicon, sample products and depositions of Ethicon employees and witnesses. The corporate documents, sample products and depositions were supplied to me by counsel. A list of Ethicon corporate documents and depositions reviewed for this report is attached hereto as Exhibit "C"; other materials reviewed are listed at the end of this report. All opinions I have are to a reasonable degree of medical and scientific certainty. I understand discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to corporate documents,

depositions and the expert reports of both Plaintiff and Defense experts. My opinions in this Report relate only to the Ethicon Design Consolidation case pending in West Virginia.

In general, my expert opinions can be summarized as follows[1]:

A. Ethicon's old construction mesh (Prolene), used in the TVT, is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence because the pores are too small, it is heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation and infections, has sharp edges, ropes, curls and deforms, and the pores collapse with tension;

B. Ethicon knew that the old construction mechanically cut mesh (Prolene) was not appropriate for use in its TVT device but has failed to modify/change the mechanically cut mesh to a larger pore, lighter weight mesh that would not deform, fray, lose particles, rope, curl, degrade, cause excessive foreign body reactions, and cause excessive shrinkage/contraction. According to Ethicon's internal documents, Ethicon was unwilling to change the mesh because of its economic interest in maintaining its competitive advantage in the MUS market and, therefore, Ethicon put profits before patient safety;

C. The Laser Cut Mesh Is also inappropriate for Use as a permanent implant because it is too stiff and rigid and causes pain and erosions and urinary dysfunction as a result

D. Ethicon's TVT's design is flawed because it cannot adequately describe, inform or explain to physicians how to properly "tension" the TVT and the mesh shrinks, contracts, ropes and curls making it difficult or impossible to tension in a safe manner for patients;

E. Ethicon's Prolene mesh in the TVT is not suitable for permanent implant because the Material Safety Data Sheets ("MSDS") for polypropylene resin used to manufacture polypropylene states that polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina;

F. Ethicon's Prolene mesh is also not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic which can cause cell death and complications;

G. Ethicon's warnings and disclosures of adverse events in its TVT Instructions for

[1] This is not intended to be an exhaustive recitation of my opinions in this case. The full scope of my opinions are described in further detail in this report.

Use ("IFU") have been inadequate based on the adverse reactions and risks associated with the TVT that have been known to Ethicon from the time the TVT was first sold and marketed, and Ethicon did not disclose information to physicians in its IFUs regarding characteristics of the old construction mesh (Prolene) that makes it unsuitable for its intended application as a permanent prosthetic implant for stress urinary incontinence, including that it is small pore, heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh, that it deforms and the pores collapse with tension, that it is difficult or impossible to tension; that it tested positive for cytotoxicity and that the MSDS states that it is incompatible with strong oxidizers such as peroxides.

H. The design of the TVT device is flawed because it is not designed for special patient populations nor does the IFU or marketing documents inform physicians that certain patients will have poorer outcomes and higher risks.

I. Ethicon failed to reveal material facts about complication and conflict of interests regarding key studies and in key marketing documents.

J. The benefits of the TVT are outweighed by the severe, debilitating and life changing complications associated with the TVT and there were safer alternative options available.

K. It has been known since the launch of the TVT that the mesh can be difficult to remove, is susceptible to degradation, can rope, curl, deform, fray, and lose particles, and is a heavy weight mesh. However, Ethicon did not account for this facts in its dFMEA at the time of launch, and has failed to complete a proper risk analysis of these hazards

III. BACKGROUND AND TREATMENT OPTIONS FOR STRESS URINARY INCONTINENCE.

A. Stress Urinary Incontinence ("SUI")

Approximately one of three women over the age of 45 years old has some form of urinary incontinence. The majority of those women do not seek medical advice or treatment for a variety of reasons.

In a continent individual, increased abdominal pressure is evenly distributed over the bladder, bladder neck, and urethra. The urethral sphincter is thus able to withstand this pressure and maintain continence. In a person with pure stress urinary incontinence (SUI),

either the urethra is hypermobile or the sphincter is intrinsically deficient. In urethral hypermobility, the urethrovesical junction (UVJ) is displaced extra-abdominally, and the increased intra-abdominal pressure is unevenly distributed such that the sphincter can no longer withstand the pressure and urine leaks. With intrinsic sphincter deficiency (ISD), the UVJ is not hypermobile; however, the maximal urethral closing pressure, the Valsalva leak-point pressure, or both are too low to withstand the increase in intra-abdominal pressure and, thus, urine leaks past the sphincter.

SUI is the involuntary leakage of urine during moments of physical activity that increases abdominal pressure, such as coughing, sneezing, laughing, or exercise, in the absence of a bladder contraction. It has been estimated that 14% of women have SUI. SUI is a common type of urinary incontinence in women. Urodynamic proven SUI is found in approximately 50% of women presenting for evaluation of urinary incontinence. Symptomatic women with SUI have social or hygienic consequence from their urine loss. SUI can happen when pelvic tissues and muscles, which support the bladder and urethra, become weak and allow the bladder "neck" (where the bladder and urethra intersect) to descend during bursts of physical activity (urethral hypermobility). This descent can prevent the urethra from working properly to control the flow of urine. SUI can also occur when the sphincter muscle that controls the urethra weakens (intrinsic sphincter deficiency). The weakened sphincter muscle is not able to stop the flow of urine under normal circumstances, and when there is an increase in abdominal pressure. Weakness may occur from pregnancy, childbirth, aging, or prior pelvic surgery. It has been estimated that a majority of incontinent women have a combination of urethral hypermobility and ISD. Other risk factors for SUI include chronic coughing or straining, constipation, obesity and smoking. Finally occult or latent SUI is defined as a positive stress test, loss of urine with increased intra-abdominal pressure and between 350-

450cc volume in the bladder, after the repositioning of pelvic organ prolapse (usually accomplished with a ring pessary carefully positioned as to avoid compression of the urethra) in an otherwise clinically continent patient.

B. Nonsurgical Treatment of SUI.

There are numerous non-surgical treatments available to woman with SUI. First, Pelvic Floor Exercises: A type of exercise to strengthen the pelvic floor by contracting and relaxing the levator muscles that surround the opening of the urethra, vagina, and rectum. These exercises, commonly referred to as Kegel exercises, improve the pelvic floor muscles' strength and function. Kegel exercises can improve over-active bladders by increasing urethral resistance with can trigger the bladder to relax.

Second, Pessary: A removable device that is inserted into the vagina against the vaginal wall and urethra to support the bladder neck. This helps reposition the urethra to reduce SUI. These can be made of rubber, latex or silicon. Inserted into the vagina, a pessary rests against the back of the pubic bone and supports the bladder. Pessaries are available in various forms, including donut and cube shapes, and must be fitted by a healthcare provider. Some women who have stress incontinence use a pessary just during activities that are likely to cause urine leakage, such as jogging. Special incontinence pessaries have a 'knob', which fits under the urethra to elevate the midurethral to prevent urine loss.

Third, Transurethral Bulking Agents: Bulking agent injections are applied around the urethra that makes the space around the urethra thicker, thus helping to control urine leakage. The effects are usually not permanent.

Fourth, Behavioral Modification: This includes avoiding activities that trigger episodes of leaking. Lifestyle modification can improve stress incontinence symptoms and include quitting smoking, weight loss, and allergy treatment during seasonal allergies.

Fifth, Urinary seals: These are adhesive foam pads, which women place over the urethral opening. The pad creates a seal and prevents the leakage of urine, providing incontinence treatment. The pad is removed before urination and replaced with a new one afterward. The pad can be worn during exercise or physical activity, but not during sexual intercourse.

Sixth, Urethral insert: A thin, flexible tube that is solid rather than hollow (like a catheter) is placed into the urethra to block the leakage of urine. These small plugs are inserted into the urethra by women to prevent leakage, and are removed prior to urination. These inserts can be uncomfortable and may increase the risk of urinary tract infection.

Seventh, Bladder neck support device: This device is a flexible ring with two ridges. Once inserted into the vagina, the ridges press against the vaginal walls and support the urethra. By lifting the bladder neck, it provides better bladder control in women suffering from stress incontinence. The device needs to be sized to fit, and must be removed and cleaned after urination. Bladder neck support devices can be uncomfortable and may cause urinary tract infections.

C. Surgical Treatment of SUI.

1. <u>The Burch Colposuspension</u>.

Retropubic approaches for the treatment of stress urinary incontinence include the Burch retropubic urethropexy (both open and laparoscopic) and the Marshall-Marchetti-Krantz (MMK) procedure. The goal of both of these procedures is to suspend and stabilize the urethra so that the urethrovesical junction (UVJ) and proximal urethra are replaced intra-abdominally and to recreate a firm backstop for intra-abdominal pressure. This anatomic placement allows normal pressure transmission during periods of increased intra-abdominal pressure restoring continence in a previously incontinent, hypermobile UVJ.

The Burch procedure was described in 1961. Initially, Burch described attaching the paravaginal fascia to the arcus tendineus. However, this was later changed to Cooper's ligaments because these were felt to provide more secure fixation points, and less chance of infection as seen with the prior MMK procedure.

Patients with type III stress urinary incontinence (a fixed, nonfunctioning proximal urethra) are not ideal candidates for a Burch procedure as no hypermobility exists to correct. For the Burch procedure, a low Pfannestiel incision is made above the pubic bone in order to enter the space of Retzius (the anatomical space between the pubic bone and the bladder above the peritonium in order to suspend the bladder and/or to perform a paravaginal repair. The procedure involves placing permanent stitches adjacent to the neck of the bladder and either proximal or distal to the bladder neck stitches on each side and suturing them Cooper's ligament which is attached to the pubic bone. The paravaginal repair is very similar except that the stitches are attached to the arcus tendentious linea pelvis. The likelihood of success of the Burch and the paravaginal repair procedures is reported to be 80-90% in most cases. Success means total elimination of the incontinence and patient satisfaction score greater than 90%. Improved means significant reduction of urine loss and greater than 70% improvement of patient satisfaction scores. Additionally, these retropubic procedures can be accomplished by the laparoscopic route. With respect to the selection of synthetic absorbable suture versus non-absorbable suture, and braided versus monofilament, no prospective randomized blinded data exist to suggest superiority of one suture material over another. However, recognized risks are associated with bone anchors. Modifications in the technique can be used if co-existent central defect cystocele is present and obliteration of the cul-de-sac can be performed to prevent enterocele or posterior vaginal wall prolapse after Burch colposuspension.

Although the Burch procedure may take longer and require a very small hospitalization,

it is a much safer procedure than synthetic slings because life-altering long-term complications do not occur with Burch like they do with synthetic slings, including chronic debilitating pain, chronic sexual dysfunction and dyspareunia, erosions, multiple surgeries to remove mesh, emotional issues related to sexual dysfunction and many others as discussed throughout this report. Furthermore, if complications do occur following a Burch procedure, they are very rarely long-term and much easier to treat.

2. <u>Pubovaginal sling procedures.</u>

Pubovaginal slings have excelled overall success and durable cure. The procedure involves placing a band of autologous, allograft, xenograft or synthetic material directly under the bladder neck (ie, proximal urethra) or mid-urethra, which acts as a physical support to prevent bladder neck and urethral descent during physical activity. This is brought up through the rectus fascia. The sling also may augment the resting urethral closure pressure with increases in intra-abdominal pressure.

Historically, surgeons have used the fascia lata sling for recurrent SUI after a failed anti- incontinence operation. Furthermore, this operation is used extensively for the treatment of primary ISD. If the abdominal tissues are weak and attenuated or if the vaginal tissues are atrophied or in short supply, constructing a pubovaginal sling from the leg fascia lata can be performed. This procedure is more involved than the creation of the rectus fascial sling as it requires a second incision to harvest the fascia lata and healing in an area remote for the index procedure.

An alternative to a long rectus sling is construction of a short sling from a much smaller piece of abdominal fascia (rectus fascia suburethral sling). The surgical procedure is similar to that used for the rectus fascia pubovaginal sling, except that the harvested fascial tissue is much smaller and the operation time shorter. The advantage of this procedure is its simplicity. No

extensive dissection in the suprapubic area is necessary, and the postoperative result is similar to that of the full-length fascial strip sling.

An alternative to a long fascia lata sling is the use of a postage stamp–sized patch of fascia lata from the outer thigh (fascia lata suburethral sling). The surgical procedure is similar to that for the fascia lata pubovaginal sling, except the harvested fascia is much smaller. This operation does not require extensive dissection in the thigh area, and the postoperative result is similar to that of the full-length fascia lata strip sling. Postoperative convalescence is shorter than that of the fascia lata pubovaginal sling procedure.

The vaginal wall suburethral sling helps restore urethral resistance by increasing urethral compression and improving mucosal coaptation of the bladder neck. This operation is attractive because it is simple and easy to perform. Postoperative complications are minimal, and the recuperative period is short. Vaginal sling surgery is relatively contraindicated in elderly women with atrophic vaginitis. If recognized before surgery, the atrophied vaginal wall may be revitalized with the administration of vaginal estrogen cream or tablets for 3-6 months.

A clear contraindication to pubovaginal sling surgery is pure urge incontinence or mixed urinary incontinence (MUI) in which urge is the predominant component. An inherent risk of any sling procedure is de novo or worsening urge symptoms; thus, surgeons must identify and treat the presence of an urge component before surgery.

Conversely, poor detrusor function is a relative contraindication to pubovaginal sling surgery because the potential for urinary retention is increased. Women with absent or poor detrusor function in the presence of SUI are at a higher risk of experiencing prolonged postoperative urinary retention.

3. <u>Midurethral Synthetic Slings</u>.

Based on the “Integral theory of female incontinence,” Prof. Ulmsten developed a

midurethral procedure to treat stress urinary incontinence. The first reports of this procedure appeared in 1996 as an intravaginal slingoplasty. The "tape'" was place through a small vaginal incision at the midurethra, brought through the urogenital diaphragm through the retropubic space and exited through small suprapubic incisions. The operation was theorized to correct incontinence by recreating the midurethral support of the pubourethral ligament and also by creating a midurethral hammock for support of the urethra during stress events. The procedure was described to have a success rate of 85-90% with an additional 5-10% significantly improved. The Gynecare TVT system was introduced in the US in November of 1998. Early studies showed that the risk of bladder perforation during the procedure occurred 5-10% of cases and vascular injury with without hematoma formation occurred in 2-5% of patients.

In an attempt to decrease the risk of bladder perforation and vascular injury, a "top-down" approach to trocar placement was promoted as the SPARC procedure, introduced in the US in 2001 by American Medical Systems (AMS). The next modification of the midurethral sling came in 2001 when Delorme described his results for the use of the obturator membrane and inner thigh for passage of the sling material. The proposed advantage was avoidance of the retropubic space, thus avoiding bladder perforation and retropubic vascular injury. The trocars were passed from the inner thigh through the obturator membrane from an "outside – in direction".

The next modification came from de Leval in 2003, with the "inside-out" trocar placement for the transobturator sling. This device is the focus of this report. The final modification came around 2006 with the release of the mini-slings, or single incision slings, which use support devices at the ends of shorter mesh lengths to accomplish fixation without the need for a secondary cutaneous exit point. The mini-slings could be placed in a retropubic

or "U" fashion or a hammock or "H" fashion.

The FDA concluded in 2011 that there was higher peri-operative blood loss, higher mesh exposure and greater need for surgical re-intervention in the TVT-Secur (mini-sling) patients.

IV. EXPERT OPINIONS

A. Ethicon's old construction mesh (Prolene), used in the TVT, is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence because the pores are too small, it is heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation and infections, sharp edges, roping and curling of the mesh, it deforms, the pores collapse with tension, and it is too stiff and rigid.

Polypropylene mesh (Prolene), like that contained in the TVT, has many well-known characteristics that make it unsuitable for use as a product intended for permanent implantation in the human vaginal floor. These characteristics include the following: (1) degradation of the mesh; (2) chronic foreign body reaction; (3) infections and bio-films; (4) fraying, roping, curling and deformation of the mesh; (5) loss of pore size with tension; (6) fibrotic bridging leading to scar plate formation and mesh encapsulation; (7) shrinkage/contraction of the encapsulated mesh; and (8) the mesh is stiff and rigid.

As a result of these and other inadequacies with the mesh, and for the reasons set forth below, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT causes a multitude of injuries, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, nerve injury of the pelvic nerves, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. For the reasons discussed further in this report and its failure to

perform appropriate long term testing and studies, Ethicon realized very early on that it had problems with the mechanically cut mesh in the TVT products, through numerous complaints from physicians. As a result, they found a cheaper way to cut the mesh and prevent particle loss and fraying through laser cutting the mesh. As a result, for the reasons discussed throughout this report, Ethicon created a stiffer, more rigid piece of mesh that created another set of complications discussed in this report. As discussed more fully below, Ethicon failed to act like a reasonable manufacture and, as a result, Ethicon's TVT-O mesh (Prolene), whether mechanically cut or cut by a laser, is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women. Ethicon failed to adequately test the laser cut mesh, silently launched the mesh and misled physicians about the laser cut mesh.

1. The Prolene Mesh in TVT Degrades Over Time

As noted below, the mesh used in the TVT was originally designed in 1974 for use in the abdomen for treatment of hernias and it has not changed since then.[2] Ethicon describes this mesh as the "old, old" mesh: "The first generation (old, old) mesh is utilized currently in the TVT product…."[3] The current Material Specifications for TVT Mesh list it as: "Old Construction PROLENE* Mesh."[4] Dan Smith testified that even when the original hernia mesh was updated for use in the abdomen, Ethicon continued to use the "old, old" mesh for TVT and does to this day, as follows:

Q: So TVT kept the old when hernia changed to the new.
A: Also known as original, yes.
Q: The mesh that was used in the TVT-R is called sometimes by Ethicon in documents old construction or original mesh; correct?
A: Yes. Yes.[5]

In the late 90's Ethicon determined that, in the hernia applications, it was safer to move

[2] Smith Dep. (2/3/2014) 723:9-724:6.
[3] Smith Dep. (2/3/2014) 723:9-724:6.
[4] ETH.MESH.10633520 at 3522.
[5] Smith Dep. (2/3/2014) 723:9-724:6.

to a lighter weight, larger pore mesh. Ethicon made a similar determination for meshes to be used in the pelvic floor.[6] However, Ethicon never updated the "old, old" hernia mesh used in the TVT.[7] Notably, in my opinion this makes science and information regarding hernia meshes and other pelvic meshes of particular relevance when discussing the TVT mesh as Ethicon chose to move to large pore, light weight meshes in these areas, but not for TVT. Moreover, Ethicon relied on science and information regarding hernia meshes to claim the safety and efficacy of their pelvic mesh products to regulatory bodies.

The placement of permanent polypropylene mesh in the human vagina creates problems because of the chemical composition and structure of the mesh and the physiological conditions of the vagina and the surrounding tissues. There have been numerous studies over the last 30 years which have shown polypropylene to be chemically reactive and not inert, with flaking and fissuring demonstrated by scanning electron microscopy, which leads to degradation and release of toxic compounds into pelvic tissues. This process enhances the inflammatory and fibrotic reactions within the tissues in the pelvic floor, causing a multitude of problems.[8] There have been studies suggesting that oxidation of the mesh occurs because of the polypropylene and the conditions in which it is placed.[9] The oxidation causes the mesh to degrade, crack and break apart.[10] In a recent study, 100 pelvic mesh implants were compared and over 20% showed degradation to mesh fibers.[11] Because

[6] See, e.g., ETH.MESH.07455220 (discussing mesh shrinkage/contracture and stating: "Since this phenomenon occurs most frequently in small pore, heavy weight mesh, ETHICON has developed large pore, light weight meshes, i.e. GYNECARE GYNEMESH PS Nonabsorbable Prolene Soft Mesh….").
[7] Smith Dep. (2/3/14) 829:16-829:19.
[8] Coda A., *Hernia 2003*;7:29; Jongebloed,WL, "*Degradation of Polypropylene in the Human Eye: A SEM Study*," Doc. Ophthalmol., 1986 64(1:143-152); Skrypunch, O.W., "*Giant Papillary Conjunctivitis from an Exposed Prolene Suture*," Can. J Ophthalmology, 198621:(5: 189-192).
[9] Costello C., et al., "*Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient*," Surgical Innovation , 2007, 143:168- 176).
[10] *Id.*
[11] Clavé A, Yahi H, Hammou JC, Montanari S, Gounon P, Clavé H, "*Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants,*" J Biomed Mater Res B Appl Biomater, 2007, Oct 83(1:44-9)

of the structural complexities of the vagina and the nature of the chemicals ordinarily found in the vagina and its surrounding tissues**,** there are several reasons why polypropylene presents unique problems when placed in the vagina. An Engineering Bulletin from Propex, entitled "*EB-405, The Durability of Polypropylene Geotextiles for Waste Containment Application,*" from 2011, states that, "[P]olypropylene is vulnerable to the following substances: highly oxidized substances such as (peroxide), certain chlorinated hydrocarbons (halogenated hydrocarbons), and certain aromatic hydrocarbons."[12] It is well known to physicians with expertise in the pelvic floor that vaginal and perivaginal tissues are ready sources for peroxide. The vaginal species lactobacillus produces hydrogen peroxide and lactic acid from collagen that is produced in the squamous cells of the vagina. Estrogen is the catalyst for the production of collagen from the vaginal cells. It is also well known that hydrogen peroxide produced by the lactobacillus species is important in controlling the vaginal micro-flora.

In fact, the vagina is a ready source of hydrogen peroxide production. In a manuscript from M. Strus, "*The In Vitro Effects of Hydrogen Peroxide on Vaginal Microbial Communities,*" the authors show the amount of hydrogen peroxide produced by the lactobacillus species.[13] "Hydrogen Peroxide reached concentrations of from 0.05 to 1.0 mm, which under intensive aeration increases even up to 1.8 mm."[14] These results confirmed the previous results of M. Strus in the publication, "*Hydrogen Peroxide Produced by Lactobacillus Species as a Regulatory Molecule for Vaginal Micro-flora*," Med Dosw Mikrobiol, 2004: 56(1:67-77).

It is also known that aromatic hydrocarbons can be found in the human body. In a

[12] *Citing* Schneider H., *Long Term Performance of Polypropylene Geosynthetics, "Durability and Aging of Geosynthetics, Koerner*, RM, Ed., (Elsevier 1989) 95-109.
[13] Strus, M., et al., *The In Vitro Effect of Hydrgen Peroxide in Vaginal Microbial Communities*, FEMS Immunol Med Microbiol, 2006 Oct; 48(1:56-63).
[14] *Id.*

paper from HB Moon entitled, "*Occurrence and Accumulation Patterns of Polycyclic Aromatic Hydrocarbons and Synthetic Musk Compounds in Adipose Tissues of Korean Females*," *Chemosphere* 2012 (86:485-490), these aromatic hydrocarbons were noted to be present in, "[t]otal concentrations of PAHs and SMCs in adipose tissues rang[ing] from 15 to 361 (mean:119) ngg(-1) lipid weight and from 38 to 253 (mean:106) nng(-1) lipid weight respectively…. The results of this study provide baseline information on exposure of PAHs and SMCs to the general population in Koreans."

It has also been determined that halogenated hydrocarbons can be found not only in adipose tissue but also the blood stream. A paper entitled, "*Determination of Volatile Purgeable Halogenated Hydrocarbon in Human Adipose Tissue and Blood Stream*," from the *Bulletin of Environmental Contamination and Toxicology*, Volume 23, Issue 1, pp 244 – 249 published in 1979, found halogenated hydrocarbons, pesticide by-products, both in human adipose tissues and the blood stream. In a subsequent paper from 1985 in *Environmental Health Perspectives*, Volume 60, pp. 127-131, Henry Anderson, in his paper entitled, "*Utilization of Adipose Tissue Biopsy and Characterizing Human Halogenated Hydrocarbon Exposure*," also found these pesticide by-products in human adipose tissue. Accordingly, the body location where the polypropylene mesh is being placed can expose it to known chemical degradation agents.

However, chemical degradation is not the only way that polypropylene degrades *in vivo*. In a paper from N Das in the Journal of Biotechnology Research International, Volume 2011, Article ID 941810, entitled, "*Review Article: Microbial Degradation of Petroleum Hydrocarbons Contaminant: An Overview*," found that various bacteria such as Pseudomonas species, Bacillus species, Mycobacterium and Corynebacterium species, which are present in a woman's vagina, can degrade petroleum hydrocarbons. Also fungi such as the Candida

species, also present, can degrade petroleum-based hydrocarbons.[15] Microbial agents that can be found inside the normal and abnormal flora of the human vagina such as Candida and, with certain pelvic infections such as Bacillus and Pseudomonas, can be a source of biological degradation of polypropylene products.

A paper entitled, "*Health, Safety and Environment Fact Sheet: Hazardous Substances - Plastics*," from CAW/TCA (www.caw.ca), August 2011:343, found that polypropylene degradation products and residues can form carbon monoxide, acrolein, aldehydes and acids, qualifying these health hazards as toxic and irritants. In a paper from D Lithner in 2011 at 4, entitled, "*Environmental and Health Hazards of Chemicals in Plastic Polymers and Products*," University of Gothenburg, it is stated that, "[n]on-biodegradable polymers can be degraded by heat, oxidation, light, ionic radiation, hydrolysis and mechanical shear, and by pollutants such as carbon monoxide, sulphur dioxide, nitrogen oxide and ozone. This causes the polymer to get brittle, to fragment into small pieces and to release degradation products." (Citations omitted.) Lithner continues, "[o]ther substances (besides monomers) are often needed for polymerization to occur, for instance initiators, catalysts, and, depending on manufacturing process, solvents may also be used. The resulting plastic polymer can be blended with different additives, for instance plasticizers, flame retardants, heat stabilizers, antioxidants, light stabilizers, lubricants, acid scavengers, antimicrobial agents, anti-static agents, pigments, blowing agents and fillers, and is finally processed into a plastic product. There are many different plastic polymers and several thousand different additives, which result in an extremely large variation in chemical composition of plastic products." *Id.* at 6 (citations omitted). "Since plastic products are composed of many different chemicals, and the main part of these [are] broken down into something completely different; this complicates the prediction." *Id.* at 8. "The type and quantity of degradation products formed may also be influenced

[15] Das, N., et al., *Review Article: Microbial Degradadtion of Petroleum Hydrocarbon Contaminants: an Overview*, J Biotech Res Intl, 2011, Article ID 941810, 1-13

by degradation mechanisms, presence of polymerization impurities, and surrounding factors, e.g. temperature and oxygen." *Id.* at 9. "Few studies combining leaching tests with toxicity tests have been performed on plastic products." *Id.* at 12. The available peer-reviewed literature regarding degradation/oxidation of polypropylene in the human body dates back to the 1960's and has been reported in numerous such publications.[16]

Two of the more important and salient articles regarding reported degradation in explanted surgical meshes (hernia and pelvic floor) are the Costello and Clave articles. In his paper, "*Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Implants from a Single Patient*," Prof. C Costello reported that hernia mesh made of polypropylene oxidized and degraded as a result of the metabolites produced by phagocytic cells during the body's inflammatory reaction to the mesh. High-magnification photographs showed cracking and peeling of the polypropylene fibers. Ethicon referenced this article in internal emails.[17]

Another article by A Clave, "*Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*," also displayed high magnification photos of polypropylene fibers from explanted meshes and, in this case, the meshes were explanted from women's pelvic floor tissue.[18] The heavyweight meshes showed even greater cracking than the lower density meshes, but according to Prof/Dr. Clave, ALL 84 of the polypropylene explants examined showed degradation. Oxidation of the implanted mesh due to free radical attack through the synthesis of peroxides, superoxides and hypochlorous acid during the chronic inflammatory phase was listed as just one potential cause for the oxidative degradation

[16] Liebert, T, et al., *Subcutaneous Implants of Polypropylene Filaments*, J Biomed Mater Res. 1976 (10:939-951); Williams, D., *Review of Biodegradation of Surgical Polymers*, J Materials Sci, 1982 (17:1233-1246); Oswald, H.J., et al., The Deterioration of Polypropylene By Oxidative Degradation, Polymer Eng Sci, 1965 (5:152-158).

[17] ETH.MESH.005588123.

[18] Clave, A., *Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*, I Urogynecol J 2010 21:261-270.

within the "septic environment" in which the pelvic meshes are placed.

Given the information available to Ethicon in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into surrounding tissues and/or migrate in the woman's body, what the clinical implications for the woman would be and whether some women's bodies would react differently to the mesh and degradative process and its by-products.

Ethicon's Daniel Burkley, a Principal Scientist at Ethicon, testified that the science supported the conclusion that mesh could shrink, contract and degrade. Specifically, Mr. Burkley agreed that the risk of degradation increases when you have a severe inflammatory response with mesh implanted in a contaminated field.[19] Mr. Burkley also testified that polypropylene mesh in human beings is subject to some slight degree of surface degradation.[20] He agreed that degradation might be better understood if Ethicon studied or tested a product that is permanently implanted in women.[21] In fact, according to Mr. Burkley, Ethicon only conducted one study related to degradation and Prolene material. This study consisted of a Prolene suture implanted into dogs.[22] Mr. Burkley testified that the study and photos from the dog actually showed that the Prolene material used in TVT degraded and was still degrading after 7 years.[23]

It is now clear from Ethicon's internal documents that Mr. Burkley was incorrect when he said that Ethicon only performed one study related to degradation of Prolene. Contrary to

[19] Burkley Dep. (5/22/13) 184:17-24.
[20] Burkley Dep. (5/22/13) 206:2-11
[21] Burkley Dep. (5/22/13) 206:12-25.
[22] ETH.MESH.05453719 (Seven year data for ten year Prolene study: ERF 85-219).
[23] Burkley Dep. (5/23/13) 315:8-13.

Mr. Burkley's claim, he and other Ethicon scientists were involved in a Prolene human explant study that was conducted in 1987 which found that Prolene degrades while in the body. According to Ethicon's documents, Ethicon's scientists received 58 Prolene human explants from Professor Robert Guidon[24] which were analyzed by Ethicon's scientists using scanning electron microscopy ("SEM"). The SEM study revealed that 34 of the 58 Prolene explants (58%) were cracked. Further studies, including FTIR and melt point analysis, were conducted by Ethicon's scientists to determine the cause of the cracking observed in Prof. Guidon's explants. In a report authored by Mr. Burkley on September 30, 1987, he concluded that the Prolene explants had insufficient antioxidants to protect them from oxidation which led to *in vivo* degradation of the Prolene devices.[25] Importantly, Ethicon has not made any changes to Prolene since it was introduced to the market, except that, in 2011, they reduced the amount of Sanatanox (another antioxidant), which could potentially make Prolene more, not less, susceptible to oxidized degradation.[26] Thus, Ethicon's internal studies clearly demonstrate that Ethicon's scientists had concluded that Prolene can degrade while implanted in the human body.

Ethicon subsequently hired an outside consulting firm to resolve the cause of the erosion of its surgical meshes for the pelvic floor. In a June 22, 2011 report, PA Consulting Group informed Ethicon that, "[p]olypropylene can suffer from degradation following implant… a process which initiates after a few days post implantation in animal studies."[27] The consulting report discusses numerous images of polypropylene mesh that show "physical

[24] DEPO.ETH.MESH.00004755
[25] ETH.MESH.12831391 at ETH.MESH.1281392
[26] ETH.MESH.02589032 and ETH.MESH.07192929 (May 18, 2011 PA Consulting Report: Investigating Mesh Erosion in Pelvic Floor Repair and PowerPoint presentations
[27] ETH.MESH.02589032 and ETH.MESH.07192929 (May 18, 2011 PA Consulting Report: Investigating Mesh Erosion in Pelvic Floor Repair and PowerPoint presentation).

degradation" of the mesh.[28] In addition, in a 2009 presentation, Ethicon Medical Director Piet Hinoul stated that meshes are not biologically inert.[29]

I have personally seen mesh that is broken, cracked, brittle and look different from when it came out of the package. Interestingly, despite years of scientific literature, its own internal dog study, performed by consultants it hired, showing that degradation of mesh occurs, and even despite the fact that Ethicon's own internal risk assessments include degradation as a known risk, Ethicon's Instructions for Use (IFU) continues to claim to this day that the mesh in the TVT "is not absorbed, nor is it subject to degradation or weakening by the action of enzymes."[30] This is not simply inaccurate, but is false and misleading for all of the reasons stated above, including, most importantly, that Ethicon's own internal documents and testimony from its employees confirm that the mesh degrades.

It is my opinion to a reasonable degree of medical certainty that the mesh used in TVT degrades. The effect of chemical and biological degradation of the TVT Prolene mesh in a woman's tissues can lead to a greater foreign body reaction, enhanced inflammatory response and excessive scarring, which can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence

[28] *Id.*
[29] ETH.MESH.01264260 (Presentation, "Prolift+M," P Hinoul, MD, Ethicon Pelvic Floor Expert's Meeting – Nederland, Utrecht, May 7, 2009).
[30] May 2015 TVT IFU; ETH.MESH.02340406

in women.

Given the information available in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into surrounding tissues and/or migrate in the woman's body, what the clinical implications for the woman would be and whether some women's body's would react differently to the mesh and the degradative process and its by-products.

Moreover, Ethicon failed to inform physicians or patients about the potential for degradation of the mesh and the complications that could follow. In fact, Ethicon not only failed to disclose these risks to physicians and patients, it did not accurately describe these significant risks by calling them "transitory" and by putting inaccurate statements about degradation in its IFU. This is information physicians need to know in order to have a fair and proper conversation with their patients about the use of a product. Physicians rely on device manufacturers to inform them of the risks and complications associated with their products instead of downplaying them or inaccurately stating them. By not disclosing this safety information to physicians and their patients, it is my opinion to a reasonable degree of medical certainty that Ethicon failed to properly inform physicians and patients about the risks of degradation of Prolene mesh in the TVT. In addition, by failing to inform physicians, Ethicon did not provide them with an opportunity to adequately discuss these risks with their patients.

2. <u>Chronic Foreign Body Reaction</u>

The human body has a natural and fairly predictable "host defense response" to any

foreign object placed inside of it. Whether a splinter or a surgical mesh, the human body will send white blood cells to attack the invader and, if the products of inflammation cannot ward off or destroy the invader, including if the invader is anything from bacteria to prosthetic implants, the initial acute inflammatory phase is followed by a chronic inflammatory phase. Therefore, with the placement of something like a permanent surgical mesh in human tissues, there will be a chronic or permanent foreign body reaction to the implant, as well as a chronic inflammatory response by the body.[31] In fact, Ethicon Medical Directors, Piet Hinoul and Charlotte Owens, have both testified that the chronic foreign body reaction created by the body's response to mesh can cause a severe inflammatory reaction, which can cause chronic pain, nerve entrapment, erosions, dyspareunia and the need for additional surgeries.[32]

Consultants and experts in the field informed Ethicon that there would be chronic tissue reaction to its polypropylene meshes. During a 2006 meeting at one of Ethicon's facilities, Bernd Klosterhalfen, a pathology consultant expert for Ethicon, informed Ethicon that there can be a continuing reaction between tissues in the body and mesh for up to 20 years.[33] In addition, during a February 2007 meeting, Ethicon stated that there can be, "[E]xcessive FBR [foreign body reaction]> massive scar plate > more shrinkage."[34]

Internally, Ethicon's scientists agreed. Dr. Holste testified that chronic foreign body reactions occurs in Ethicon's small pore, heavyweight meshes like the Prolene mesh found in TVT.[35] In fact, Dr. Holste testified that Ethicon developed lighter weight, large pore meshes in order to minimize the complications seen with heavyweight meshes like the Prolene used in

[31] Klinge, U., et al., *Shrinking of Polypropylene Mesh In Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164: 965-969; Klinge, U., *Foreign Body reaction to Meshes Used for the Repair of AbdominalWall Hernias,*Eur J Surg 1998, 164:951–960; Klostherhalfen,B., *The lightweight and large porous mesh concept for hernia repair*, Expert Rev. Med. Devices 2005, 2(1); Binnebosel M, et al., *Biocompatibility of prosthetic meshes in abdominal surgery*, Semin Immunopathol 2011, 33:235-243; ETH.MESH.03658577 (Biocompatibility of Ultrapro).
[32] Hinoul Dep. (4/5/12) 99:09-25; (4/6/12) 518:14-520:20; (6/26/13) 175:1-176:17;184:18-22; 328:10-24; Owens Dep. (9/12/2012) 98:11-99:07.
[33] ETH.MESH.00870466 (June 6, 2006 Ethicon Expert MeetingMeshes for Pelvic Floor Repair, Norderstedt).
[34] ETH.MESH.01218361 (Ethicon Presentation: "State of Knowledge in 'mesh shrinkage'-What do we know").
[35] Holste Dep. (7/29/13) 52:5-55:21.

TVT.[36] Ethicon employee, Christophe Vailhe, testified that there can be an excessive inflammatory reaction or foreign body reaction that would lead to mesh erosion and contraction.[37] Despite its knowledge about the problems associated with chronic foreign body reaction, Ethicon continues to use a heavyweight, small pore mesh in its TVT product.

Contrary to this scientific evidence, Ethicon informed doctors in its IFU that its TVT mesh was "non-reactive with a minimal and transient foreign body reaction," until the IFU was updated in 2010 to remove the word "transient"[38] This was despite all of the internal documents and testimony discussed above from Ethicon's Medical Affairs and Research and Development employees that chronic foreign body reaction occurs in small pore, heavyweight meshes like the Prolene mesh in TVT. Moreover, as one of Ethicon's lead engineers stated:

"the foreign body reaction is not transitory – it doesn't ever go away, but decreases over time to a minimal level."[39] That is, it is chronic. I have reviewed numerous pathology reports from my own patients and other physician's patients and pathology reports reviewed in litigations describing foreign body reactions. Hence, the mesh potentiates a chronic, long-term inflammation. This is contrary to the express language of the TVT IFU up until 2010 and, to this date, the IFU still does not state the foreign body reaction is chronic.

Even before Ethicon launched the TVT with the heavyweight, old construction mesh for sale in the United States. Ethicon knew that Prolene mesh was far from being the ideal material for use in vaginal tissues.[40] However, despite knowing this, Ethicon decided to launch the product for use in repair of anterior prolapse, in order to gain entry into the market before competitors. Ethicon also knew that doctors had expressed fears about rejection and problems with removing the mesh at a later date, fear of infection, concern that the mesh could erode into

[36] Holste Dep. (7/29/13) 51:3-53:6.
[37] Vailhe Dep. (6/21/13) 383:8-19.
[38] ETH.MESH.02340406; ETH.MESH.02340531; TVT IFU, May 2015
[39] ETH.MESH.00211259
[40] ETH.MESH.12009027

the bladder or rectum, and concern about the stiffness of the mesh and the risk of the mesh protruding through the vagina. Even knowing of these concerns regarding the use of Prolene mesh in women's vaginal tissues, Ethicon proceeded to launch the TVT with the heavyweight, 1974 old construction Prolene mesh.

For the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT creates a chronic foreign body reaction which can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon failed to inform physicians or patients about the potential for a severe, chronic foreign body response and the complications that could follow. In fact, not only did Ethicon fail to disclose these risks, it mischaracterized the risks by calling them "transitory" and by putting inaccurate statements about foreign body response in its IFU. This is information physicians need to know in order to have a fair and proper conversation with their patients about the use of a product. Physicians rely on device manufacturers to inform them of the risks and complications associated with its products instead of downplaying them or inaccurately stating them. By not disclosing this safety information to physicians and their patients, it is my opinion to a reasonable degree of medical certainty that Ethicon failed to properly inform physicians and patients about the risks of foreign body response of Prolene mesh in the TVT. In addition, by

failing to inform physicians, Ethicon did not provide them with an opportunity to adequately discuss these risks with their patients.

3. Infections/Bio-films

The placement of midurethral slings, including TVT, violates one of the most basic tenets of surgical teachings in that it is the placement of a permanent implant into the patient through a "clean contaminated" surgical field, *i.e.* the vagina, which is not sterile and can never be completely sterilized.

In TVT, the weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing polysaccharide slime (biofilm), which further serves to shield the bacteria from destruction by white blood cells and macrophages.[41] The effect and consequences of biofilm is to increase the foreign body reaction, resulting in chronic infections, chronic inflammation, erosions, and mesh and scar contracture, and was well known to Ethicon, as evidenced by the testimony of Ethicon's Head of Pre-Clinical, Dr. Joerg Holste.[42]

Importantly, the biofilm actually serves as a protection for the bacteria surrounding the mesh fibers against the body's host defense response (white blood cells), which are intended to destroy foreign invaders like bacteria. Thus, the weave induces the creation of a shield against the body's defenses to the bacteria entrained in the woven mesh, inhibiting the body's ability to fight off the infective agents within the mesh. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh

[41] Osterberg, B., et al., *Effect of Suture Materials on Bacterial Survival in Infected Wounds: An Experimental Study*, Acta. Chir. Scand 1979, 145:7 431-434; Merritt, K., *Factors Influencing Bacterial Adherence to Biomaterials*, J Biomat Appl 1991, 5:185-203; An, Y., *Concise Review of Mechanisms of Bacterial Adhesion to Biomaterial Surfaces*, J Biomed Mater Res (Appl Biomat) 1998, 43:338-348; The TVM Group: J. Berrocal, et al., *Conceptual advances in the surgical management of genital prolapsed*, J Gynecol Obsted Biol Reprod 2004, 33:577-587.
[42] Holste Dep. (7/30/13) 295:24-298:14, 411:15-414:24.

during the insertion process.[43] Daniel Burkley testified that reducing surface area could reduce the amount of chronic inflammation.[44] Additionally, the size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses leading to numerous complications.[45]

There have been numerous peer-reviewed journal articles regarding secondary-mesh related infections as well as the dangers of implanting surgical mesh in a clean/contaminated field. Of note, in May of 2013, at the AUA meeting in San Diego, Dr. Shah and his colleagues reported on the "*Bacteriological Analysis of Explanted Transvaginal Meshes*," which included explanted samples of both SUI slings and prolapse meshes. Of the 50 explants examined, 52% of those explanted due to patient complaints' of painful mesh were infused with pathogenic organisms, 20% of those explanted due to vaginal erosions had pathogenic organism, and 83% of those explanted due to urinary tract erosions were contaminated with pathogenic organisms.[46]

When polypropylene particles separate from the surface of the mesh fiber due to degradation, see infra, the surface area of the mesh is greatly increased thus providing even greater areas for bacterial adherence to the mesh, more elution of toxic compounds from the polypropylene, and also more of the free toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of the fibrosis.[47] This cracking of the mesh surface also provides safe harbors for infectious bacteria to proliferate.

In his periodic histopathological analyses for Ethicon of its pelvic floor explants, Dr.

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[43] Klinge, U., et al., *Do Multifilament Alloplastic Meshes Increase the Infection Rate? Analysis of the Polymeric Surface, the Bacteria Adherence, and the In Vivo Consequences in a Rat Model*, J Biomed Mater Res 2002, 63:765-771; Vollebregt, A, et al., *Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: Are Additional Intraoperative Sterility Procedures Useful?*, Int Urogyn J 2009, 20:1345-51.
[44] Burkley Dep. (5/22/13) 371.
[45] Klinge, *supra* n. 26; Vollebregt, *supra* n. 26.
[46] Shah, K., et al., Bateriological Analysis of Explanted TransvaginalMeshes (Abstract 1144).
[47] Jongebloed, *supra*, n. 1; Sternschuss, G, et al., *Post-Implantation Alterations of Polypropylene in the Human*, J Urol 2012, 188:27-32; Clave, *supra*, at 6.

Klosterhalfen reported to Ethicon that, in virtually 100% of those instances in which mesh had been explanted due to erosions, he found a secondary, mesh-related infection at the tissue/mesh interface.[48] Mesh exposure and erosion cause the fibers to be further exposed to bacteria that will adhere to and colonize on the mesh surface.

Ethicon employees have testified that they were aware of these biofilms forming on the surface of the mesh.[49] However, Ethicon never performed any long-term, clinical studies to determine whether the warnings given them through the peer-reviewed literature and by their own experts and consultants were accurate, namely that mesh-related infections are real; that they cause patient injury in the form mesh erosions and recurrent, late infections; and that the transvaginal implantation through and into the non-sterile, septic vagina is below the standard of care for any surgical technique, especially one used to treat non-life threatening conditions, such as stress urinary incontinence.

Therefore, it is my opinion to a reasonable degree of medical certainty that the TVT mesh is susceptible to biofilm formation due to the weave of the mesh allowing the infiltration, harboring, and protection of bacterial contaminants; the degraded mesh surface harboring bacteria; the passage through and into a clean/contaminated field; and after exposure/erosion of the mesh into the vagina or other organs, further contamination of the mesh with a multitude of vaginal flora that further increases the risk of harmful and recurrent infections in women. Accordingly, the TVT transvaginal technique, as well as the TVT mesh itself, are not safe for their intended purpose of implantation into a woman's pelvic tissues and can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual

[48] ETH.MESH. 00006636.
[49] Holste Dep. (7/30/13) 283:19-284:5.

dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Finally, Ethicon's claims in its IFU that the TVT mesh may "potentiate infection" are misleading, at best. If, by the intentionally ambiguous term, "potentiate," Ethicon means "cause," then this is true for all of the reasons stated above. If by "potentiate," Ethicon means "exacerbate an existing infection," then the statement is misleading at best. Ethicon failed to warn physicians and patients that a slimy, protective biofilm could form on the mesh leading to painful erosions, recurrent, late infections and the need for mesh removal. The TVT IFU contrasts sharply with the PROLENE IFU on this issue. The PROLENE IFU states as follows: PROLENE Mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.[50]

Ethicon did not to include this risk, despite that unlike hernia mesh, TVT mesh is being implanted through a contaminated environment – the vagina. By failing to include this risk, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity to discuss these risks with their patients.

4. <u>Pore Size and Fibrotic Bridging</u>

Fibrotic bridging occurs when the fibers surrounding the pores of the mesh are too close together to allow the tissue in the pore enough room to recover from the trauma of tissue damage due to implanting a surgical prosthetic device. Pores that are large enough for good, newly- vascularized tissue tend to be filled with fatty tissue versus small pores that become

[50] ETH.MESH.02342102.

filled with scarred or fibrotic tissue. In those instances, the scar forms across the pores or "bridges" from one side of the pore to the other. This can occur either due to the granulomas around the mesh fibers joining together or due to densely-formed fibroblasts between these granulomas. Either way, such bridging can lead to the creation of a rigid, scar plate that can encapsulate the mesh with scar tissue. Simply put, small mesh pores that cause fibrotic bridging turn the mesh into a solid sheet of scar tissue and there is no space or room for tissue to grow into the mesh, which is the intended purpose of the mesh. The fibrotic bridging and scar plate prevents tissue in-growth and causes complications, including, among other things, pain with the rigid mesh, shrinkage or contraction of the mesh, erosions due to mechanical irritation in the tissue of a rigid, scar- plated mesh, nerve entrapment, chronic pain and dyspareunia.

This concept is best illustrated by a DVD produced by Ethicon which features an Ethicon consultant, Dr. Todd Heniford, talking about a heavyweight, small pore mesh called Marlex used for hernia repairs.[51] The Prolene mesh used in TVT is of heavyweight, small pore construction and, in fact, is even heavier than Marlex. Ethicon Scientists have acknowledged that the Marlex mesh in the video is similar to the Prolene in TVT in that is heavy weight small pore mesh.[52] Ethicon has also relied on the works of Dr. Heniford relating to lightweight mesh and cited to his works in their marketing materials and professional educational materials for pelvic mesh products. Moreover, Ethicon relied on science and information regarding hernia meshes to claim the safety and efficacy of their pelvic mesh products to regulatory bodies. At least one medical director at Ethicon, Dr. Thomas Divilio, has described the work done by Dr. Heniford and others as "material science" that would apply

[51] Heniford, B.T., 2007, *The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair*, Video produced by Ethicon.
[52] ETH.MESH.05918776 (5/04/04 Email from Schiaparelli, Jill, Strategic Grown Subject: Marlex Experience); Batke Dep. (8/01/13) 87:12 - 88:10, 113:3-114:3, 257:23-259:13; Holste Dep (7/29/13) 51:3-53:6, 55:22-57:4; Vailhe Dep. (6/20/13) 182:2 185:5.

to both hernia and pelvic mesh products. In my opinion this the video, as well as other science and information regarding hernia meshes and other pelvic meshes of particular relevance when discussing the TVT mesh as Ethicon chose to move to large pore, light weight meshes in these areas, but not for TVT.

In the video, Dr. Heniford talks about the dangers of heavy weight, small pore meshes.[53] In fact, Dr. Heniford states, "there is no excuse for using heavy weight, small pore meshes in the human body."[54] I have explanted numerous TVT and TVT meshes and have witnessed meshes with extensive scar plating and mesh encapsulation similar to the hardened/stiffened mesh viewed in the Heniford video. In numerous emails, Ethicon employees discussed concerns regarding fibrotic bridging.[55] They have testified that the heavy weight, small pore type of mesh in the TVT can lead to an increased risk of foreign body reaction, contraction of the mesh, nerve entrapment, erosions and chronic pelvic pain.[56] In other emails, when discussing these concepts, Ethicon's World Wide Marketing Director for General Surgery, Marty Chomiak, states that "… we want to avoid 'bridging', therefore we think large pores are better than small . . ."[57] Ethicon also had information and scientific knowledge regarding superior mesh designs to prevent fibrotic bridging and scar plating. Specifically, Ethicon also had scientific knowledge that light weight, large pore mesh could decrease the likelihood of foreign bodyreaction, fibrotic bridging and scar plating.[58]

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[53] Heniford Video, supra, n. 46.
[54] *Id.*
[55] ETH.MESH.04037600 (Innovations in mesh development); ETH.MESH.05920616 (7/20/07 ; Emails from Chomiak, M. to Batke, B., et al. re Defining light weight mesh); ETH.MESH.05585033 (Boris Batke Presentation – Project Edelweis – Ultrapro); ETH.MESH.05446127 (3/13/2006 Emails from Holste, J. to Engel, D., et al re Mesh and Tissue Contraction in Animal – "Shrinking Meshes?); ETH.MESH.05475773 (2/09/2007 Boris Batke, Ethicon R&D, Presentation: *The (clinical) argument of lightweight mesh in abdominal surgery*); ETH.MESH.04015102 (3/1/12 Email from Batke, Boris to Mayes, C. re AGES Pelvic Floor Conference-Gala Dinner Invitation); ETH.MESH.04037600 (3/15/12 Boris, B. PowerPoint Presentation, *Innovations in Mesh Development*,Melbourne AGES 2012).
[56] Batke Dep. (8/1/13) 87:12-88:10, 113:3-114:3, 257:23-259:13; Holste Dep. (7/29/13) 51:3-53:6, 55:22-57:4; Vailhe Dep. (6/20/13) 182:2-185:5.
[57] ETH.MESH.05920616 (7/20/07 Email from Chomiak,M. re Defining LightWeightMesh).
[58] Batke Dep. (8/1/13) 87:12-88:10, 113:3-114:3, 257:23-259:13; Holste (7/29/13) 51:3 - 53:6, 55:22 - 57:4; Vailhe

Despite having clinical knowledge of the importance of pore size to successful outcomes, and dozens of emails about the importance of pore size, Ethicon's person most knowledgeable about pore size testified that Ethicon does not manufacture its mesh to a specific pore size. Dan Smith testified as follows:

> Q: Does Ethicon have a validated test method to determine the pore size of its TVT mesh?
> A: We determine the pore size by courses and wales and that is how it's done. So the courses and wale count is a validated test method.
> Q: And I'm talking about pore size. Does Ethicon have a validated test method to determine its pore size for its mesh?
> A: The construction of the mesh is -- does not have a pore size requirement.[59]

In fact, Ethicon does not even have a test to measure the pore size of its mesh. Dan Smith testified:

> Q. Mr. Smith, does Ethicon have a validated test to describe the pore size of its TVT meshes microns? Yes or no.
> A. No….[60]

Despite this information that it did not measure pore size or manufacture its mesh to a specific requirement, Ethicon repeatedly stated in advertising and marketing materials that its mesh was "large pore." For example, in one brochure, Ethicon promotes the mesh used in the TVT family of products (including TVT) as the "Largest pore size" of any of its competitors, listing the size as 1379 um.[61] However, given that Ethicon has no verified methodology to measure pore size, Ethicon had no scientific basis upon which to base these statements. In fact, in internal documents, Ethicon scientists described PROLENE mesh as small pore: "Standard Mesh PROLENE small pores area weight 105 g/m2."[62] One Ethicon Engineer measured a mesh and determined that there were two pore sizes in the mesh, a "major" and "minor" pore. "There are two distinct pore sizes in

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Dep. (6/20/13) 182:2-185:5.
[59] Smith Dep. (2-3-14) 729:1 to 729:12.
[60] Smith Dep. (2-3-14) 779:5 to 779:8.
[61] ETH.MESH.00349508 at 9510.
[62] ETH.MESH.04941016.

the PROLENE 6 mil mesh (TVT). The major pore is about 1176 um…. The minor pore is about 295 um."[63] Certainly, neither of these pores was 1379 um, and the minor pore was substantially smaller.

In addition, the pore size of a mesh can change when the mesh is put under stress such as when a sheath is removed or the mesh is tensioned. Dan Smith agreed that these stresses can make an effective pore size smaller than 1 mm.

> Q. You would agree, Mr. Smith, that if the measurement across the pores we're looking at here -- let's assume you measure across one of those pores and let's say it's more -- let's say it's 1 millimeter across hypothetically. If a load is put on the mesh and it changes the pore size, that pore could be, after a load is put on it, under 1 millimeter; correct?
> A: It's possible depending on the load.[64]

Ethicon engineer Christophe Vaihle testified that "excessive tension on the mesh would lead to the decrease in pore size that can lead to poor tissue integration . . . ."[65] Ethicon has done nothing to change the mesh and continues to promote and sell the product with the same, heavy weight, thick filament "Old Construction 6 mil" mesh that they have been selling since 1974 (Prolene), despite what Ethicon considers to be "revolutionary" advancements in polypropylene mesh design that it brought to other pelvic floor polypropylene mesh products.[66] In summary, for the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT causes fibrotic bridging in the body, resulting in an increased inflammatory response leading to a multitude of injuries, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, dyspareunia that can be chronic, nerve injury, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal

[63] ETH.MESH.00584175 (Ex. T-3583); ETH.MESH.00584179 (Ex. T-3581).
[64] Smith Dep. (2/3/2014) 816:5 to 816:15.
[65] Vailhe Dep., (6/20/13) 224:10-226:21.
[66] ETH.MESH.03905968; *see also* Prolift +M CER ("As the mass of a mesh implant is reduced and the pore size is increased, the surface area exposed to the host is reduced, and the foreign body reaction to the implant is reduced.").

scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon did not inform physicians and patients that its mesh was susceptible to fibrotic bridging. Ethicon failed to warn physicians and patients that fibrotic bridging could occur leading to painful erosions, recurrent, late infections, nerve injury and the need for mesh removal. By failing to do so, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity adequately to discuss these risks with their patients.

5. Mesh Contracture/Shrinkage

Mesh contracture or shrinkage is an event that takes place after the implantation of mesh and relates to the wound healing process that occurs after the surgical trauma of implanting a foreign body made of polypropylene in the sensitive tissues of the vagina and pelvis. By 1998, polypropylene mesh was known to contract or shrink 30-50%.[67] These findings were later confirmed in numerous papers, such as those by W. Cobb and his colleagues – one of whom was Dr. Henniford (referenced above).[68] This also showed that heavier weight meshes like TVT led to greater amounts of contraction. The works of Cobb and Klinge/Klosterhalfen have been referenced in numerous Ethicon documents. Contraction or shrinkage has been shown to draw nerves close to the midurethral sling mesh both in the transobturator application[69] and for retropubic application.[70] Furthermore, contraction or

[67] Klinge, U, *Shrinking of Polypropelen Mesh in Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164:965-969.
[68] Cobb, W., et al., *The Argument for Lightweight Polyropylene Mesh in Hernia Repair*, Surgical Innovation 2005, 12(1):T1-T7.
[69] Corona, R., et al., *Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy*, J Min Invas Gynecol 2008, 15:3, 262-267; Parnell, B.A., et al.,*Genitofemoral and Perineal Neuralgia after Transobturator Midurethral Sling*, Obstet. Gynecol 2012, 119:428-431; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Intl Urogyn J, 2009,

shrinkage is closely related to the pore size and weight of the mesh. Small pore, heavy weight mesh leads to fibrotic bridging which leads to scar plates, mesh encapsulation and shrinkage or contraction of the mesh, which is compounded by the shrinkage effect associated with the normal wound healing process already occurring in the tissue.

This phenomenon of shrinkage and its relation to the design of the pores as well as the consequences to the patient were illustrated in an email by Ethicon Scientist Joerge Holste in a March 13, 2006 email discussing a paper he authored entitled "Shrinking Meshes?"[71] In his email, Dr. Holste states "this was our scientific statement on mesh shrinkage: Basically, small pores, heavy weight meshes induce more fibrotic bridging tissue reaction causing more mesh shrinkage during maturation of the collagenous tissue. See my presentation about biocompatibility."[72] In addition, in a presentation by Boris Batke, Associate Director R&D, he states heavier-weight polypropylene mesh results in mesh contraction of 33%.[73] In an email dated November of 2002, related to a discussion of mesh used in a TVT product, Axel Arnaud, one of Ethicon's medical directors, used 30% shrinkage of the mesh as a "rule of thumb."[74] At an Ethicon expert meeting in Norderstedt, Germany in 2007, an Ethicon employee presented a PowerPoint entitled "Factors Related to Mesh Shrinkage" in which all of these issues were clearly laid out.[75]

Mesh shrinkage was known by Ethicon as early as 1998 in published work by Ethicon's

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20:893-6; Tunn, R, *Sonomorphological Evaluation of Polypropylene Mesh Implants After Vaginal Mesh Repair in Women with Cystocele or Rectocele*, Ultrasound Obstetrics Gynecol 2007, 29:449-452.

[70] Heise, C.P., et al., *Mesh Inguinodynia: A New Clinical Syndrome After Inguinal Herniorrhaphy?*, J Am Coll Surg.

[71] ETH.MESH 05446127, *supra*, n. 34.

[72] *Id.*

[73] ETH.MESH 05479717 (3/1/11 Boris Batke, Ethicon Associate Director R&D, Presentation: Ethicon PolypropyleneMesh Technology).

[74] ETH.MESH 03917375.

[75] ETH.MESH. 02017152 (Nordestadt Expert's meeting 2007); ETH.MESH.01782867 (Factors Related to Mesh Shrinking).

then consultants, Uwe Klinge and Bernd Klosterhalfen.[76] They noted in these early papers that all polypropylene meshes shrink 30-50%. This was restated in later works by W Cobb and his colleagues[77]--one of which was Dr. Heniford (referenced above). The words of Cobb and Klinge/Klosterhalfen have been referenced in numerous Ethicon documents and thus, Ethicon was well aware of these findings regarding the shrinkage or contraction of polypropylene meshes in vivo. Ethicon was further aware that heavier weight meshes led to greater amounts of contraction. And, notably, Ethicon equated the tissue reaction in the abdomen to heavyweight mesh to the tissue reaction in the pelvis to heavyweight mesh in marketing materials, professional educational materials and regulatory materials.

It is my opinion to a reasonable degree of medical certainty that as a result of work with internal and external experts and consultants in the late 1990s, multiple internal documents and articles, and the scientific literature as a whole, that Prolene mesh used in TVT not only could, but would shrink and contract, and that this shrinkage could lead to painful complications in women implanted with TVT, such as multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, nerve injury, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women, and Ethicon failed to warn physicians and patients of the possibility of shrinkage and

[76] Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998: 164; 965-969
[77] ETH.MESH.07455220.

contraction and the adverse outcomes that could occur as a result.

6. Fraying, Particle Loss, Roping and Curling, Deformation and Loss of Pore Size

Ethicon designed the TVT mesh such that, when stress was put on the mesh, particles would separate from the mesh – this was called fraying or linting.[78] One of Ethicon's engineers described this as a "defect" that resulted from the method of cutting the mesh: "The mesh frayed is the reverse defect of the mesh features (elasticity of the mesh is one of the commercial arguments to market the TVT)…. [T]he root cause of this phenomenon are known: the way to cut the mesh (blade cutting). If we change the way to cut the mesh (ultrasonic cutting or laser cutting) it seems we can limit the mesh frayed defect significantly…."[79]

As early as 2000, Ethicon's engineers documented that particles from TVT Prolene mesh fell into women's tissues as a result of the tape edges being damaged during sheath removal.[80] In April 2001, Dr. Alex Wang, "one of the most experienced TVT users in the world," reported problems with frayed mesh and uneven tape width.[81] Although the issue was described as "serious" and as requiring "urgent attention and solution," Ethicon Medical Director, Dr. Martin Weisberg, simply concluded that the deformity in the mesh would be unlikely to have any clinical significance. Dr. Weisberg testified that although he did not actually know whether frayed mesh leading to particle loss would have clinical implications, he does not recall whether he or anyone else at Ethicon studied the issue.[82] Just a few months later, however, Ethicon received a complaint by an experienced surgeon regarding a patient

[78] Weisberg Dep. (5/31/13) 461:7-462:3 ("Q. So engineers within the company knew that fraying of the product was inherent in the design? A. Yes.").
[79] ETH.MESH.01813975 at 2 (Ex. 3160/3587).
[80] ETH.MESH.01317515 (7/12/00 Preventia TVT-2 Risk Analysis Procedure/Tensioning Frayed Mesh/Particle Loss). at 7523.
[81] ETH.MESH.03905472 (6/4/01 Emails from Wang, A. re TVT Recommendation for Ethicon Study of Fraying/Particle Loss).
[82] Weisberg Dep. (5/31/13) 469:23-470:16.

who experienced vaginal wall erosion following a TVT procedure which was first noted by her husband during intercourse.

According to the surgeon, "the tape appeared frayed and tiny fibers were protruding through the vaginal wall."[83] In November 2003, Dr. Weisberg reported that there had been a total of 58 complaints of fraying with TVT since introduction of the device in 2000. He observed that the following occurs when the mesh frays: "[T]he mesh elongates in places; the mesh narrows in places; and small particles of Prolene might break off … and that [s]tretching of the mesh increases the probability of fraying."[84] Once again, however, Dr. Weisberg concluded that "since fraying does not affect the safety and efficacy of the TVT device, it has been determined not to pursue any corrective actions at this time."[85] Dr. Weisberg confirmed during his deposition that no corrective action was taken and, although he did not know whether Prolene particles could elicit a chronic foreign body response, he does not recall whether he or anyone else at Ethicon investigated the issue.[86]

In 2004, Ethicon continued to receive complaints from surgeons about fraying and "brittle" mesh and particles falling into the operating field.[87] One of the company's "most urgent customers," Swiss surgeon Dr. J. Eberhard, wrote the following: "Already at the operation it is embarrassing to see how the tape is crumbling. But it gets worse if there is stretch on the tape.… I can't understand that no one will solve that problem for such a long time. As the latest, as the tape has becoming blue, everyone has realized that the quality of the tape is terrible."[88]

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[83] ETH.MESH.02621559 at 2276 (Ethicon Issue Report TVT Retropubic 2001 Open Date Between 01- Jan-2001 and 31-Dec-2001).
[84] ETH.MESH.00541379 (11/18/03Memo fromWeisberg re Mesh Fraying for TVT Devices Inadequate Testing).
[85] *Id.*
[86] Weisberg Dep. (5/31/13) 469:23-470:16.
[87] ETH.MESH.00863391 at 3392 (2/27/04 Emails from Smith, D. re 2 TVT Complaints Concerning Allegedly Brittle Mesh).
[88] ETH.MESH.02180833 (11/12/04 Letter from Prof. Dr. Eberhard (translated)); ETH.MESH.02180828 (11/12/04 Telefax from Sibyll, B. re Prof. Dr. Eberhard).

Dan Smith, the Lead Engineer on TVT lamented the particle loss that was revealed when the mesh was dyed blue: "This is not going away anytime soon and competition will have a field day, major damage control offensive needs to start to educate reps and surgeons UPFRONT that they will see BLUE shit and it is OK."[89] Indeed in November 2004, one of the "top 3 complaints" included "Mesh frayed."[90] Once again, however, Ethicon decided to take no corrective action.[91] Instead, sales representatives were instructed to reassure their doctors that, "Prolene is proven to be inert," the "particles will not cause any problem," and to "be proactive" because "the competition will try to target this!"[92] Physicians were told the particles are "non- reactive" and that fraying does not affect the safety or efficacy of the device.[93] In fact, it has consistently been Ethicon's position that frayed mesh and resulting particle loss as well as roping, curling and deformation of the mesh do not create a safety risk and have no clinical significance.[94]

However, as noted above, Ethicon never tested whether the particles would cause pain in women.[95] Moreover, Ethicon never specifically tested whether the particles, or frayed, curled shrunken and deformed mesh, would cause pain when in close proximity to the pelvic and vaginal nerve bundle and muscles. An independent investigator, Dr. Pariente, did and published a study that concluded that "the very high particle shedding for both Sparc (AMS) and TVT (Ethicon) may be of significant long term clinical concern in some quarters."[96] In addition, Ethicon collected data from physicians who informed Ethicon that particles could,

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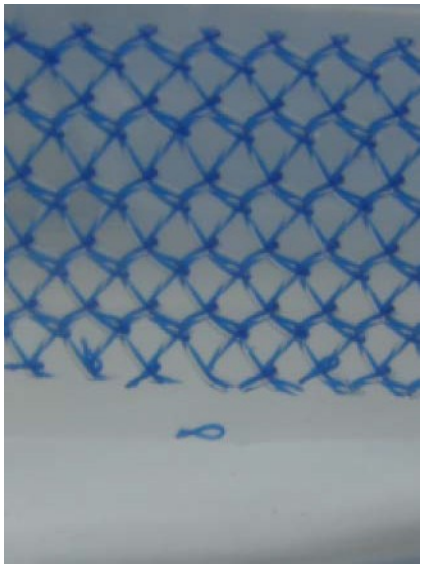
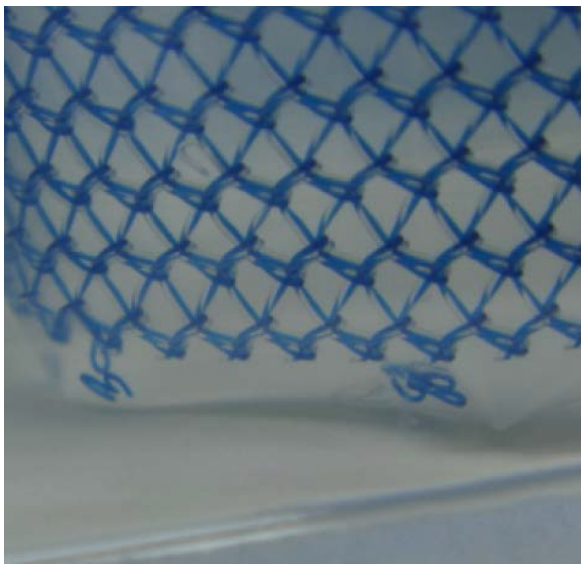
[89] ETH.MESH.00863391.
[90] ETH.MESH.01813975 (Ex. T-3160 / T-3587).
[91] ETH.MESH.02180826 (11/12/04 Email fromMenneret, D. re Mesh Fraying: Dr. Eberhard Letter).
[92] ETH.MESH.00865322 (3/2/04 Email from Bell, S., Ethicon Marketing Director Europe to Sales & Marketing Team re Reminder on Blue Mesh – Frayed Mesh/Particle Loss).
[93] ETH.MESH.03535750 (10/12/2005 Hunsicker, K., Ethicon Clinical Operations Regional Manager, Presentation: *Investigator Initiated Study Process – Inadequate Testing*).
[94] ETH.MESH.00541379, *supra*, n. 58; ETH.MESH.00858252 (2004 Memo from London Brown, A. re Mechanical Cut v. Laser Cut Mesh Rationale).
[95] Trial Testimony of Piet Hinoul, Batiste v. Ethicon, page 26-28.
[96] ETH.MESH.01221055 (Pariente, J-L, *An independent biomechanical evaluation of commercially available suburetheral slings*, Issues in Women's Health 2003).

indeed, cause pain and dyspareunia.[97] Moreover, Ethicon medical director Piet Hinoul testified the particles that fall of the mesh create inflammation and inflammation can cause pain.[98] Although Ethicon claims that its own internal testing shows approximately 1% particle loss with TVT,[99] Dr. Pariente's study demonstrated TVT particle loss as high as 8.5% - 10 times higher than most of its competitors.[100] In addition, Ethicon's April 2006 Clinical Expert Report on Laser Cut Mesh suggested there was a decrease in particle loss with laser cut mesh and this "decrease would lead to less non-functioning material left in the tissues."[101] It cannot be disputed that the greater the nonfunctioning material left in a patient's tissues, the greater the surface area of polypropylene the patient is exposed to, and the greater the inflammatory responses and the greater the foreign body response. As discussed above, the long term consequences of this chronic foreign body reaction and inflammatory response can be, among other things, chronic pain, lifelong risk of erosions, dyspareunia and failure of the device. If the individual flakes work their way through the vaginal mucosa, this can lead to dyspareunia and/or painful intercourse for the partner as noted in the complaint received by Ethicon back in 2001 referenced above. The larger the surface area the greater the risk associated with vaginal mesh. Finally, detached flakes of polypropylene may migrate into the vasculature or lymphatics and cause problems remote from the pelvis. For these reasons, Ethicon should have used a mesh without a fraying and particle loss defect when selling its TVT for permanent implant in a woman's vaginal tissues.

Ethicon continued to receive complaints related to particle loss from the mechanically cut mesh in the TVT. In 2010, customers complained that they were seeing pieces of mesh in

[97] ETH.MESH.05644163 at 4166 (Dr. Hilton, one of Ethicon's principal investigators in the TVT v. Burch trial, informed Ethicon that: "The small particles migrate and cause pain during intercourse.").
[98] Trial Testimony of Piet Hinoul, Batiste v. Ethicon, page 26-28.
[99] ETH.MESH.000585802; ETH.MESH.00585842; ETH.MESH.00585823 06/27/06 (Email from Kammerer, G. re GY: ***URGENT*** French STANDARD ON TVT & MESHES (COMMENTS REQUIRED)).
[100] ETH.MESH.01221055, *supra*, n. 67; ETH.MESH.00585842 (6/12/06 Email from Kammerer, G re TVT LCM –
[101] ETH.MESH.00167104 at 7109.

the unopened packages. Ethicon employees initially responded that "No, this is not nor do we recommend using the product." Pictures from Ethicon's complaint file reveal particles of the mesh that have begun to break off from the mesh inside the package. [102]

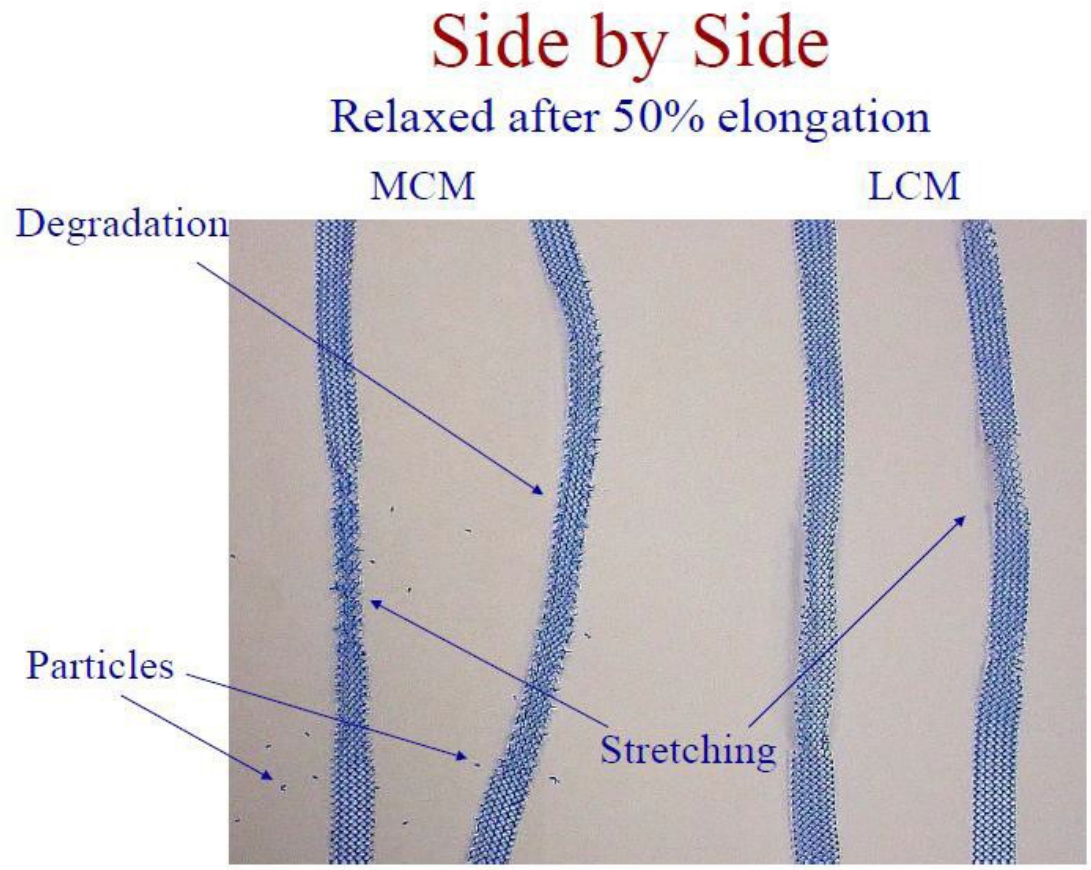
Nine packages with particles of lose mesh were returned to Ethicon for analysis. I have requested to examine these products, but have been told that Ethicon has discarded these products.[103] Ethicon employees later reversed their position on the mesh particles stating that: "mesh particles of this size are common with the manual cutting process and are within our specifications. The product is safe to use."[104] This conclusion seems to be at odds with internal manufacturing documents indicating that nearly 2,000 TVT and other mesh products were rejected because of foreign matter in the product or packaging during the month of March, 2010 alone at Ethicon's Neuchatel manufacturing facility.[105] Ethicon's conclusion that the products were safe to use does not appear to be a result of any scientific or engineering study of the returned products,

[102] ETH.MESH.13204508.
[103] Letter from Ben Watson to Andrew Faes, April 16, 2015; Letter from Andrew Faes to Ben Watson, March 25, 2015.
[104] ETH.MESH.13226457.
[105] ETH.MESH.13907354-55.

but rather the conclusion of Ethicon Medical Director David Robinson that "…the possibility for the tiny tape fragments observed… … to cause adverse consequence in a patient… … should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile."[106] It is my opinion to a reasonable degree of medical certainty that this conclusion is incorrect and not supported by any study or clinical evidence gathered by Ethicon. In fact this conclusion is belied by the fact that Ethicon told the same physicians who complained about the particles that they may wish to consider TVT mesh manufactured with a laser cutting process that does not result in tiny mesh particles within the package.[107] Because of dangers associated with loose particles, fraying and deformed mesh, described more fully below, the mesh from this TVT mesh posed unreasonable dangers to women and Ethicon should have never allowed the mechanically cut mesh in the TVT to be offered for sale for implantation in women. In addition to fraying and particle loss, the mechanically cut meshes used in TVT has also been shown to rope, curl and deform when under tension. In 2006, an Ethicon Engineer, Gene Kammerer, made a presentation that clearly showed each of these defects in the mechanically cut mesh. These photos clearly show particle loss, fraying, degradation, roping

and deformation when the mechanical cut mesh was stretched and compared to TVT Laser Cut.[108]

[106] ETH.MESH.04101014.
[107] ETH.MESH.13226457.
[108] ETH.MESH.08334245.



As noted these photos show mesh after 50% elongation. I have read depositions of Ethicon personnel claiming this is not a realistic elongation seen with mesh. However, Ethicon's engineer who took the photos, Gene Kammerer, explained that he had experienced it himself in testing:

> The link between the elongation percent, not force, and the integrity of the mesh is this. During the operative procedure as the surgeon removes the protective sheath from the mesh, the mesh stretches or elongates. It is my experience, after viewing many surgical procedures and performing numerous procedures on cadavers myself, that the mesh stretches approximately 50% at the maximum. There is also additional stretching that occurs if the surgeon elects to do an adjustment on the position of the mesh under the urethra. It is these two occurrences which produce the majority of the particle loss and loss of the integrity of the construction of the mesh.[109]

Again, Ethicon claimed that these problems with the mesh did not have any clinical

[109] ETH.MESH.00584811.

significance despite the fact that surgeons were complaining.[110] However, Ethicon's own internal documents demonstrate that this is not true. According to Ethicon's Failure Modes documents, the loss of pore size due to mesh narrowing or deformation can lead to urinary retention or erosion. Ethicon's own dFMEA from 2006 shows that the hazards of curling/roping, frayed edges and inadequate pore size of mesh can lead to the harms of erosion, recurrence, and pain.[111]

When discussing the dFMEA for Laser Cut Mesh, Former Medical Director, David Robinson, agreed that pore size of both the Laser Cut and Mechanically Cut mesh "[c]ould reduce, the tissue might not encapsulate . . . the tissue might not grow through the mesh. It can become encapsulated and then it could cause . . . a rejection of the mesh."[112] And, Dr. Robinson testified that rejection of the mesh can lead to erosion.[113] These changes in the mesh may lead to erosion or pain for women with the deformed mesh implanted in their bodies. Further, according to Ethicon, this curling, roping or narrowing of the mesh may also cause urinary retention in addition to erosion and pain.[114]

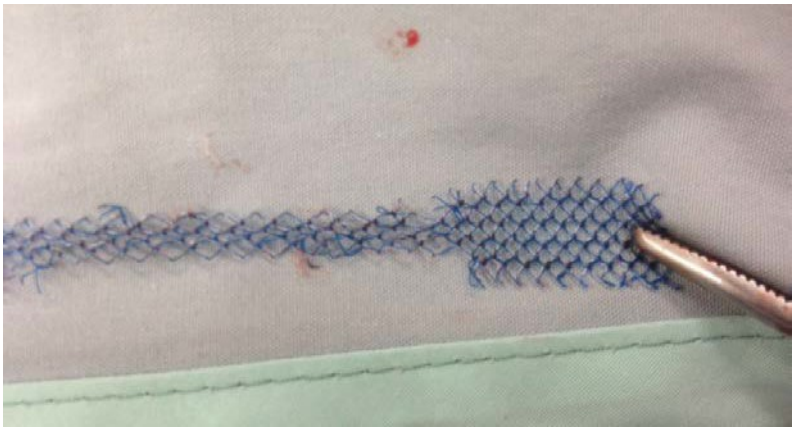
In fact, I have witnessed the same type of roping and narrowing of TVT when I placed them myself. I see the deformed and roped mesh when I remove them. This localized pressure under the urethra leads to complications like, among others, urinary retention, chronic pain, dyspareunia and erosions. In addition, I have reviewed Ethicon TVT training videos that show the exact problem discussed about related to deformation and roping of the "tape" under the urethra.[115] Finally, according to Ethicon's Dan Lamont, it chose to continue to sell "mechanically cut mesh despite knowing that it had the potential for degradation, particles

[110] ETH.MESH 00440005; ETH.MESH 00302390 (TVT-Base & TVT Review for Laser Cut Mesh (LCM) Risk Analysis).
[111] ETH.MESH.01218019.
[112] Robinson Dep. (9/11/13) 1070:23-1072:25.
[113] *Id.*
[114] Robinson Dep. (9/11/13) 1079:3-4-1081; 1081:9-13; 1083:8-18; ETH.MESH.01218019.
[115] ETH.MESH.PM.000004 (TVT Retropubic Implantation Video).

floating around in women's bodies, stretching, and roping . . ."[116] Lamont admitted that the fraying of the mesh was a "defect" of the mesh.[117]

Not surprisingly, Ethicon continues to receive complaints related to the mechanical cut mesh used in TVT fraying, roping and curling. Recently, the highest volume user of TVT products in Canada, Dr. Kenny Maslow, complained to Ethicon that the mesh used in TVT would fray down to a thin fiber even with "very little tension applied to the sling."[118]

Dr. Maslow included a picture of the frayed mesh used in TVT when he reported the issue to Ethicon.



[116] Lamont Dep. (9/11/13) 30:18-24.
[117] Lamont Dep. 9/11/13) 15:16-16:10.
[118] ETH.MESH.12910023.

Another feature of mechanically cut mesh is its sharp edges as shown on this photo:[119]

While Ethicon states that these sharp edges are part of the intended "velcro" effect of mesh, it was a feature about which Ethicon had received complaints tied to injuries and erosions. For example, during on market research test with physicians, it was reported:

> The surgeon felt that the MCM strips was elastic but with "hairs" on the edges and that it scratched with abrasive texture scraping (like the Scotch -BriteTM pads), furthermore a lot of particles were released and a rope/string effect could occurred if an excessive force was applied.[120]

In fact, when one agency recognized a spike in erosions, it inquired whether this was a result of "the cut ends of the tape appear to be sharper and more likely to cut tissue."[121] A sentiment shared by some physicians and reported to Ethicon:

> Basically, he thinks that erosions due to the TVT mesh are underestimated in reports. The reason is that in order to recognize them, a very careful vaginal examination is needed. Most of the time, a "hidden" erosion is asymptomatic and neither the patients nor their sexual partner if any complain. But it might happen that a patient may complain. He believes that erosion are due to the

[119] ETH.MESH.09656795.
[120] ETH.MESH.06696589.
[121] ETH.MESH.00330760.

> sharp edges of the mesh. He wanted to suggest that we add to the mesh edges a kind of seam that would help preventing erosion.[122]

Dr. Axel Arnaud responded that Ethicon did not want to modify its mesh (even if it caused erosions) because Ethicon did not want to lose the marketing edge of using the Ulmsten/Nilsson data. He wrote:

> I also indicated that we want to be very careful with any modifications of our tape since a change in the mesh would obsolete all the long term clinical results we have about the procedure.[123]

However, the market pressure on Ethicon to create a laser cut mesh without particle loss, roping and deformation became very strong. Paula Evans, Gynecare European Marketing Manager, described the situation as "France is in a recovery mode, Germany is hemorrhaging business … Without laser cut, there is the real risk that more business will be lost."(sic)).[124] Hence, the laser cut mesh project went forward presumably in an effort to address the chronic problems with particle loss, fraying, sharp edges and elongation seen with mechanically cut mesh.[125]

During early development of laser cut, Ethicon acknowledged that mechanical cut mesh and laser cut mesh were two separate mesh products and to imply otherwise would be misleading. In December 2005, Kevin Mahar described the marketing strategy "…KEEP selling regular TVT (the 'Colonel's Original Recipe') to those customers that want/love it…and KEEP going forward with 8 years of data, etc with the original recipe … We do not mislead them that this is the same product…"[126] In discussing that document, Dr. Robinson verified that Mahar was referring to the mechanically cut mesh as the Colonel's Original

[122] ETH.MESH.03911107 (Axel Arnaud reporting his interview with Professor Hausler).
[123] *Id.*
[124] ETH.MESH.04985249.
[125] ETH.MESH.00301741 (11/21/05 Email from Lamont, D. re !!!!GREAT NEWS FOR TVT LASER CUT MESH!!!! –Frayed mesh/particle loss); ETH.MESH.00394544 (2/01/06 Global Regulatory Strategy – GYNECARE TVT – Laser Cutting Project);Weisberg Dep. (5/31/13) 487:13-488:7.
[126] ETH.MESH.00687819 (Ex. T-3164).

Recipe:

> Q: He writes, "While we" -- "While we would work with our agency to get this right, my thoughts are that we keep selling regular TVT," meaning the mechanically-cut mesh, right?
> A. Yes.
> Q. "(The Colonel's 'Original Recipe') to those customers that want/love it." Right?
> A. Yes.
> Q. Talking about a piece of plastic that is permanently implanted in a woman's body as the "Original Recipe," right?
> A. That -- yes, that's correct.[127]

Ethicon initially decided that particle loss, elongation curve and flexural rigidity data on laser cut would not be required because they were not "critical to quality." In fact, this news was celebrated as "!!!!!GREAT NEWS FOR TVT LASER CUT MESH!!!!" and "less work for all of us."[128] However, because Ethicon wanted to continue to claim the marketing benefit of the Ulmsten/Nilsson series, marketing determined that some testing was needed. This was described as a way to protect the "clinical heritage" of the mesh:

> Marketing Need: Keep clinical heritage intact…. In order to continue to claim the use of 7-year data and all clinical studies, the MCM and LCM needed to show similar properties with the physical properties being used as a proxy for the clinical needs.[129]

Ultimately, Ethicon did not end up telling doctors that the mechanically cut mesh and the laser cut mesh are essentially the same, a decision that has kept doctors in the dark about the defects inherent in the mechanically cut TVT mesh, and has led to continued harms and hazards to women. In my opinion as a physician, Ethicon's decision to continue to market and sell the mechanically cut mesh, with all of its defects, and the decision to market the improved laser cut mesh as virtually the same as the old construction (Prolene) mesh, was clearly a decision by Ethicon to put profits before patient safety. In summary, for the reasons set forth

[127] Robinson Dep. (7/25/13) 585:12-23.
[128] *Id.*; ETH.MESH.00584291 (2/15/06 Email from Flatow, J.re DVer protocol for particle loss).
[129] ETH.MESH.00858252; *see also* ETH.MESH.00526473; ETH.MESH.02248778 (Kammerer PPT); Hellhammer Dep. (9/11/13) 120-121.

above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT has several characteristics that make it improper for use in the vaginal canal including particle loss, fraying, roping, curling, deformation and loss of pore size. These unwanted characteristics can lead to, among other things, an increased inflammatory response (particle loss and fraying) and/or increased pressure on the urethra (roping or curling) or loss of pore size (roping or curling), and can lead to a multitude of injuries, including such as multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon did not inform physicians and patients that its mesh was susceptible to these physical deformations that could lead to painful erosions, recurrent, late infections and the need for mesh removal. Nor did Ethicon inform physicians that laser cut mesh had materially different mechanical properties than mechanically cut mesh. By failing to do so, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity to discuss these risks with their patients.

B. Ethicon knew that the old construction mesh (Prolene) was not appropriate for use in its TVT device as early as 1998, but failed to modify/change the mesh to a larger pore, lighter weight mesh that would not deform, fray, lose particles, rope, curl, degrade, cause excessive foreign body reactions, and cause excessive shrinkage/contraction because of its economic interest in maintaining its competitive advantage in the MUS market and, therefore, Ethicon put profits before patient safety.

As stated above, Ethicon knew from the time it launched the TVT with the mechanically cut mesh that it was defective in multiple respects. This is true because the TVT Prolene mesh was known to be made from heavyweight 6 mil fiber and a construction that allowed for mesh curling, roping, fraying, zipping, particle loss, and sharp edges. In fact, beginning in 1998, Ethicon had already established a "mesh improvement project" in order to improve the mesh. Despite the fact that the project yielded an improved mesh, Ethicon never incorporated those improvements into the TVT.

As early as May of 1997, Ethicon knew that the Prolene mesh was not ideal for use in vaginal tissues.[130] In fact, Ethicon knew of a case at that time were a patient had been treated with Prolene mesh, which protruded through the vagina, requiring excision of the mesh. Ethicon knew that the ideal mesh for use in the vagina should not have any fraying or spiky edges, needed to have large enough pores to encourage in-growth, and should have a low mass density to minimize foreign body reaction.[131] Ethicon then embarked on a project to improve the Prolene mesh used in the TVT product and Ethicon's hernia products. Among the characteristics they sought to improve were the product curling, zipping and unraveling of the mesh after cutting, and crumbling of the mesh.[132] Ethicon noted that if the Prolene mesh was pulled in one direction, the mesh would curl up into a tube, and the mesh would remain in a rolled condition even after the force of the pulling was no longer on the mesh.

[130] ETH.MESH.12006257
[131] ETH.MESH.12006257
[132] ETH.MESH.09264945

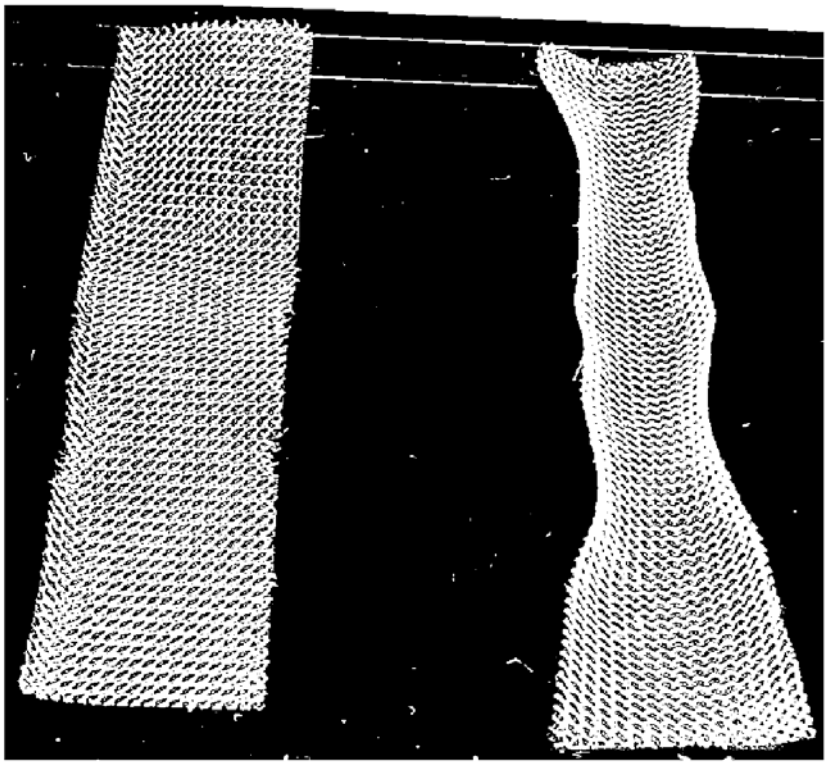


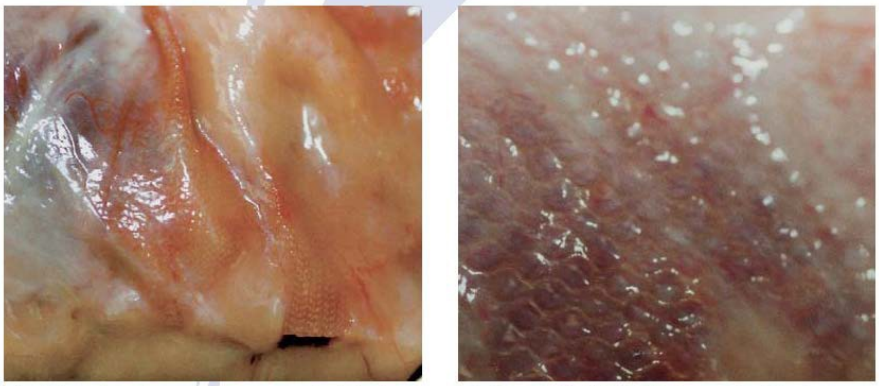
Figure 1 – Control mesh sample before and after the application of the force. A clear picture of mesh curling results.

Ethicon also referred to the original construction 6 mil Prolene mesh as a mesh that was known for its "bad" curling quality.[133] Ethicon ultimately changed the flat Prolene mesh used for hernia repair to address these issues, making changes to the construction of the mesh to address the bad curling quality of the mesh, and at the same time, changing to a lighter weight, 5 mil mesh construction.[134] The change in the mesh construction also made the mesh less likely to fray and lose particles.[135] Despite Ethicon's original intent to incorporate the new construction material which was lighter weight and had improved resistance to curling, fraying, and particle loss,[136] Ethicon continued and still continues to use the original, old, old heavyweight 6 mil construction

[133] ETH.MESH.02182844, ETH.MESH.00946834.
[134] ETH.MESH.00782152.
[135] ETH.MESH.020008684.
[136] ETH.MESH.09264884.

mesh for the TVT products.[137]

The flaw in the construction of the TVT heavyweight Prolene mesh which allows it to curl into a tube after tensioning or pulling on the mesh and not return to its original shape, combined with the heavyweight and small pore nature of the mesh, causes the mesh to fold up and become hard post-implantation. Ethicon continued to be aware of this continuing defect in the mesh well



Traditional polypropylene mesh. 90 days post-implantation. Fold development (in-vivo study)

Lightweight VYPRO* II mesh. 90 days post-implantation. Fold-free incorporation (in-vivo study)

after the Prolene mesh improvement project was completed and the company changed the construction of its Prolene hernia mesh.[138] Ethicon was also aware that lightweight materials were less likely to fold up post implantation and integrated better with surrounding tissues,[139] but continued to use the heavier 6 mil fibers. The lightweight materials were also much better at resisting crumpling and less likely to have sharp edges during tissue integration.[140]

Ethicon continued to have problems with mesh quality in the TVT mesh after the Prolene mesh improvement project was complete, but never incorporated those changes into the TVT mesh. After the improved construction 5 mil Prolene mesh replaced the 6 mil mesh Prolene mesh for flat hernia repair, Ethicon noted continuing problems with the Prolene mesh

[137] ETH.MESH.09275875, ETH.MESH.02030355.
[138] ETH.MESH.05918776.
[139] ETH.MESH.05446129.
[140] Ethicon Tissue Reinforcement Solutions, 8/21/2004.

in the TVT, noting inconsistent tape width,[141] and fraying and particle loss from the TVT mesh.[142] Doctors reported to Ethicon that the quality of the mesh was terrible, and that particles were falling off the mesh, which was worse when the mesh was elongated.[143]

Even before the TVT was launched in the United States, Ethicon was looking at ways to change the existing mesh tape construction in order to improve the appearance of the mesh and to alleviate problems experienced during the manufacturing process.[144] Ethicon also knew prior to launching the TVT for sale in the United States that if the tape became twisted, it would reduce the effectiveness of the TVT procedure, and evaluated laser-cut samples of the TVT mesh as opposed to the mechanically cut mesh.[145] The project which looked at laser cutting the mesh was part of the "TVT improvement project" which began prior to the launch of the TVT in the United States. Included in the goals of the TVT improvement project were a mesh that was safer, eliminated abrasion, rough edges, and narrowing of the mesh under tension.[146] Ethicon evaluated feedback from surgeons who compared the Laser cut mesh to the guillotine (mechanically) cut mesh, and were told that the laser cut mesh had a more regular appearance, the mesh did not stretch as much as the current guillotine cut mesh, and there was a marked reduction in the amount of loose ends falling off.[147] Testing also showed that the mechanically cut mesh stretched 90% more than the laser cut mesh when force was applied to the mesh. However, despite having a laser cut mesh available which had less rough edges, less particle loss, and less narrowing and deformation under tension, Ethicon chose to launch the TVT in the United States with the guillotine (mechanically) cut mesh.

Ethicon did not change the Prolene mesh in its TVT device despite having better and

[141] ETH.MESH.12002601.
[142] ETH.MESH.00863405.
[143] ETH.MESH.02180833.
[144] ETH.MESH.10591870.
[145] ETH.MESH.12009079.
[146] ETH.MESH.12009262; ETH.MESH.12009276.
[147] ETH.MESH.10182456.

safer options available for economic reasons. Ethicon believed that continued use of the TVT mesh gave the company an economic and competitive advantage in marketing the product because they could continue to use the existing clinical data on the product to market the device, while if the mesh was changed, the existing clinical data would be obsolete.[148] Dr.

Brigitte Hellhammer testified that despite having incorporated the use of the lightweight, large pore Ultrapro mesh in vaginal tissues for the treatment of pelvic organ prolapse, the Ultrapro was never used by Ethicon in a device used for the treatment of stress urinary incontinence largely because the company wanted to continue to rely on the Ulmsten/Nilsson series of studies on 130 patients performed with the TVT device. [149] Dr. Arnaud also confirmed that the company did not want to change anything with the mesh because of the exiting clinical data on the product.[150] It is my opinion to a reasonable degree of medical certainty that Ethicon was negligent in failing to correct the defects in the TVT mesh as the company had knowledge of the defects and failed to correct the defects with products and solutions that were already available to the company because it put its economic interests above the safety of patients.

C. The TVT Laser-Cut Mesh is also innapropriate for use as a permanent implant because it is too stiff and rigid and causes pain and erosions and urinary disfunction as a result

Ethicon started manufacturing and selling the TVT with laser cut mesh in late 2006. The laser cut Prolene mesh in the TVT is cut with a laser in the manufacturing process, as opposed to being mechanically cut.[149] This means that the plastic mesh is cut into strips using a laser instead of a cutting blade.[150] The result is that the mesh itself is stiffer than mechanically cut mesh.[151] In fact, an internal memo from Becky Leibowitz to Paul Parisi and Dan Smith in late 2004 found that

[148] ETH.MESH.03911107.
[149] ETH.MESH.00576844; ETH.MESH.03546997; Smith Dep. (5/15/14) 48:11-17.

[150] Lamont Dep. (9/11/13) 12:13-13:14.
[151] ETH.MESH.01809080-01809081.

when the laser cut mesh was stretched it became about three times stiffer than the machine-cut TVT mesh.[152] Just four years later, it is noted that no clinical study had been done regarding the differences between laser cut mesh and mechanical cut mesh.[153] Nevertheless, Ethicon began regarding its use of the stiffer laser cut mesh.[154] Importantly, while these discussions about the differences between laser cut mesh and mechanical cut mesh were going on, most surgeons using the TVT products did not know what type of mesh they were using.[155] Thus, there was no way for doctors to adjust tensioning differently or be aware that the mesh is stiffer, or to warn patients of an increased risk of erosions and pain. Even as late as February 2015, Ethicon still had not done a single study to determine whether the laser cut mesh causes more erosions than mechanical cut mesh, whether laser cut mesh increases the amount of pain a patient will experience, or any critical outcomes.[156]

The difference in the stretch profile between mechanically cut and laser cut mesh also led Carl G. Nilsson and Christian Falconer, two of the inventors of the original TVT,[157] and Jean de Leval, the inventor of TVT-O, to refuse to use, and question the use, of laser cut mesh.[158] Moreover, according to the J&J Defendants, use of the laser cut mesh would make them unable to rely on the original studies and data they use to tout the safety and effectiveness of the original TVT.[159] Additionally, laser cut mesh was never assessed on its own in a clinical trial.[160]

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[152] ETH.MESH.01809080
[153] ETH.MESH.02090196.

[154] ETH.MESH.00576844.

[155] ETH.MESH.009911296.
[156] Trial Testimony of Katrin Elbert, *Perry v. Luu, et al.*, (2/11/15) 3433:27-3434:18.

[157] Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, et al. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. Int J Urogynecol J Pelvic Floor Dysfunct 1998;9:210 –3.

[158] ETH.MESH.16416002-16416004; ETH.MESH.04048515-04048520.

[159] ETH.MESH.06040171-06040173.
[160] ETH.MESH.03941617.

Ethicon's Medical Director, Piet Hinoul, even noted in 2011, after the launch of the TVT Exact, that there was is no literature that allows him to discriminate which clinical trials have used laser cut versus mechanical cut.[161]

It is now well known among surgeons and in the published literature that stiff, rigid mesh increases the risk of complications and injuries to women.[162] Based on my experience, training, review of the literature, and review of Ethicon's internal documents, it is my opinion that the laser cut mesh in the TVT is defective because it is too stiff and rigid. As a result, the mesh increases complications including but not limited to chronic pain, chronic dyspareunia, erosions, and urinary dysfunction.

D. Ethicon's TVT's design is flawed because it cannot adequately describe, inform or explain to physicians how to properly "tension" the TVT and the mesh shrinks, contracts, ropes and curls making it impossible to tension.

TVT stands for and has consistently been marketed by Ethicon as "Tension-free Vaginal Tape." Presumably, this means the mesh should be inserted under the urethra without tension. However, the term "tension-free" is misleading. In practice, too little or no tension results in failure to treat the underlying condition of urinary incontinence. On the other hand, as suggested by Ethicon's own internal documents, too much tension can result in serious complications such as retention and urethral erosion.[163] Also, as discussed above, because the mesh shrinks, contracts, ropes and curls, it is impossible or extremely difficult to properly tension the mesh.

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[161] ETH.MESH.00576844. Notably, Dr. Hinoul's trial testimony in *Batiste v. Ethicon*, is in direct contradiction to his statement in this email that all of the TVT-Os tested in his study were laser cut. Presumably in order to convince the doctor to use the laser cut.

[162] Nolfi AL, Brown BN, Liang R, Palcsey SL, Bonidie MJ, Abramowitch SD, Moalli PA, Host Response to Synthetic Mesh in Women with Mesh Complications, *American Journal of Obstetrics and Gynecology* (2016), doi: 10.1016/j.ajog.2016.04.008. Moalli et al, Presentations 8 through 10, Female Pelvic Medicine & Reconstructive Surgery • Volume 17, Number 5, Supplement 2, September/October 2011

[163] ETH.MESH.05529274;ETH.MESH.04044797; ETH.MESH.05529653; ETH.MESH.00161131.

The IFU provides little guidance on proper tensioning of the TVT. Specifically, once the tape is placed, surgeons are simply instructed to pull the needles upwards "to bring the tape (sling) loosely, i.e. without tension, under the midurethra" and to "adjust the tape so that leakage is limited to no more than one or two drops."[164] The IFU's Warnings and Precautions section cautions surgeons to "[e]nsure that the tape is placed with minimal tension under the mid-urethra."[165] Yet in the very same section, the surgeon is instructed "to place the tape tension-free in the mid-urethral position" to minimize the risk of de novo detrusor instability.[166] Finally, the IFU's "Adverse Reactions" section provides that "over correcting, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction."[167] The IFU's conflicting instructions with regard to tensioning of the tape, "without tension," "with minimal tension," "tension-free" and "overcorrecting, i.e. too much tension" are clearly confusing and inadequate despite the fact that Ethicon knew as early as 2000 that improper tensioning could lead to complications and, therefore, the IFU needed to be "clear."[168] These tension issues are compounded when the mesh contracts, shrinks and deforms as discussed above.

Ethicon recognized as far back as November 1999 that TVT tension adjustment was considered "high need" and surgeons had a hard time sticking to proposed technique.[169] By 2000, Ethicon recognized that excess tensioning during initial placement could create a risk of erosion.[170] In an email dated February 13, 2001, Medical Director Axel Arnaud wrote "there is clearly a need for standardization of the TVT procedure to avoid excessive tension on the mesh. We should aggressively work in order to develop a product and I would like to take the

[164] Eth.Mesh.05222686, emphasis added.
[165] Eth.Mesh.05222687, emphasis added.
[166] Eth.Mesh.05222567, emphasis added.
[167] Eth.Mesh.05222687, emphasis added.
[168] Eth.Mesh.01317523.
[169] Eth.Mesh.05641096.
[170] Eth.Mesh.05529274; Eth.Mesh.04044797; Eth.Mesh.05529653; Eth.Mesh.00161131.

responsibility for this."[171] In May 2002, Axel Arnaud continued to recognize the need to develop a safer device "in order to prevent excess tension of the tape."[172] In 2003, Ethicon recognized that a challenge with the TVT procedure remained complications "associated with over-tensioning of the sling and the inability to obtain precise biofeedback and adjustment during and/or after the procedure."[173] Indeed, Dr. Nilsson, the "father of the TVT", discussed that the TVT done under general anesthesia with a cough test was 70% successful compared to a 85% success rate when done with local anesthesia and a cough test.[174]

The lack of clear direction on tensioning in the IFU is demonstrated in September 2004 emails from Sales Representative Shannon Campbell in which she writes: "What is a huge challenge to a rep trying to make this right, is that we really don't know what the right amount [of tensioning] is. We know this is a quick fix to the problem, but not a clinically backed solution. It's almost like trying to decide if a 8, 10, or 12 mm Hagar dialator is best for tensioning TVT with the patient under general. We learned the cough test, but relied on surgeons experience with the tensioning under general…. This has been such a gray area and everyone seems to have their own tensioning technique." She continues: "I feel I got a little grilled over my suggestion of tensioning, yet there is no clear direction on tensioning. I'm not a rebel looking for my own way of doing this. I'm a rep trying to figure out what is best from my experience with surgeons and what I see the product doing in the OR. …The reason for my question is to see if someone had the proper wording we need to use as rep's that eliminates our liability with the product in the OR concerning tensioning."[175]

In December 2006, Ethicon Marketing Director Allison London-Brown referred to tensioning as a "sticky" question and acknowledged that "we cannot accurately describe

[171] Eth.Mesh.03915380.
[172] Eth.Mesh.03907468.
[173] Eth.Mesh.00259271.
[174] Eth.Mesh.04048515 at Eth.Mesh.0408516 7/01/08 KOL Interview: Carl G. Nilsson, Project Scion.
[175] Eth.Mesh.00864503.

[tensioning] in writing."[176] Meanwhile, Ethicon knew that patients were suffering from erosions and, in fact, would often blame the physician as the cause of the erosion for putting "too much tension on the device."[177] At least by 2007, it seems Ethicon finally acknowledged that "TVT has never been tension free!" despite years of marketing it otherwise.[178] For example, in 1999, Ethicon utilized marketing pieces for "TVT Tension Free Vaginal Tape" which claimed "Tension-free Support Only When Needed" which "reduces possibility of urethral erosion."[179] A 2001 marketing piece for "Gynecare TVT Tension-Free Support for Incontinence" claimed "most complications are minor and are avoidable with adherence to procedural technique and instructions for use."[180] In 2004, during the same time period when Shannon Campbell was lamenting the problems with tensioning, Ethicon continued to promote TVT as "the leader in midurethral sling devices" for 'tension-free support for incontinence."[181] Even after Ethicon acknowledged that TVT has never been tension free, the company continued to market it as "Tension-free Support for Incontinence.[182]

Physicians were also not informed in Ethicon's product IFU that tension on the mesh arms decreases effective pore size and interferes with incorporation into tissue. Engineer Christophe Vailhe testified that "excessive uniaxial tension on the mesh will decrease the pore size and lead to poor tissue integration."[183] In addition, Mr. Vialhe testified that "excessive tension on the mesh would lead to the decrease in pore size that can lead to poor tissue integration . . . ."[184] Engineer Dan Burkley also testified that once the TVT Prolene mesh is either stretched by the surgeon or stretched by in-vivo due to forces in a women's body, it can

[176] Eth.Mesh. 01784428-01784435.
[177] Eth.Mesh.02625055, Eth.Mesh.02627811, Eth.Mesh.02625375, Eth.Mesh.02625155.
[178] Eth.Mesh.06861473.
[179] Eth.Mesh.00161444.
[180] Eth.Mesh.00339437.
[181] Eth.Mesh.00160813.
[182] Eth.Mesh.00164643; Eth.Mesh.00339053.
[183] Vailhe, 6/20/13, 224:10-226:21.
[184] Vailhe, 6/20/13, 224-226.

alter the structure of the pores.[185]

The IFU failed to adequately instruct surgeons on the critical subject of tensioning as repeatedly acknowledged by Ethicon. Ethicon now claims that "tension-free" does not really mean tension-free, but rather, means less tension than as seen in the Burch procedure.[186] Yet, despite its awareness of the problems associated with tensioning, Ethicon failed to revise the conflicting and ambiguous IFU to provide adequate direction on the proper amount of tensioning even though Ethicon was fully aware that improper tensioning could lead to serious complications such as urinary retention, voiding difficulties, de-novo detrusor instability, dyspareunia, vaginal extrusion and urethral erosion. In addition, the design of the device and the mesh is problematic because it shrinks, contracts and deforms exacerbating the issues discussed above.

Ethicon failed to act as a reasonable and prudent medical device manufacturer by failing to design the TVT in a way that it could be properly tensioned and by failing to inform physicians how to properly tension TVT and that improper tension could affect the pore size of the mesh. These failures by Ethicon have resulted in numerous injuries to patients, including, but not limited to chronic pain, urinary retention, voiding difficulties, de-novo detrusor instability, dyspareunia, and vaginal extrusion and urethral erosion.

As one sales representative noted in an email to Dan Smith, the inability of Ethicon to properly communicate how to tension the TVT had safety and legal ramifications:

> I feel I got grilled on my suggestion of tensioning, yet there is no clear direction on tensioning…. My goal is not to get the tape changed, yet strive to place the mesh as designed without altering it. The surgeon does own the responsibility of proper delivery and placement. The fact is, they look to us as reps to show them the proper placement techniques.
> The reason for my question is to see if someone had the proper wording we need to use as reps that eliminates our liability with this product in the OR concerning

[185] Burkley 5/22/13 430:3-431:10.
[186] Smith 6/4/13 524:20-525:13.

tensioning.[187]

In my opinion, Ethicon failed to properly test the unique tensioning issues related to the TVT prior to marketing the device. Ethicon left physicians without sufficient information about how to properly remove sheaths and/or properly tension the TVT mesh in light of the lack of uniformity with tensioning and for failing to account for problems with the mesh like contraction, shrinkage and deformation when tensioning. Ethicon improperly managed the sheath/tension problem by telling individual physicians "tips and tricks" including the Surgeon's Resource Monograph. This advice necessarily could not reach hundreds of surgeons who did not get the "tips and tricks" from sales representatives or Ethicon employees. Such information should have been put in the IFU. Because physicians did not have the proper information, they could not impart the information to their patients or properly consent their patients for all of the risks associated with over-tensioning mesh such as roping, curling, fraying and all of the associated injuries.

E. Ethicon's Prolene mesh in the TVT is not suitable for permanent implant because the Material Safety Data Sheets ("MSDS") for polypropylene resin used to manufacture polypropylene states that polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina

According to Ethicon Medical Director, Dr. Martin Weisberg, a Material Safety Data Sheet (MSDS) is "a document that discusses the product, the composition, any potential hazards from it . . . Generally, the safety particular of products."[188] As it relates to polypropylene, I have reviewed several MSDSs for polypropylene resin used to manufacturer meshes used in various pelvic floor meshes. All of the MSDSs discussed below are available to the public.

Sunoco, the manufacturer for the polypropylene resin used to manufacture Ethicon's

[187] ETH.MESH.00864503.
[188] Weisberg Dep. (8/9/13) 909:2-9.

pelvic floor products lists the possibility that polypropylene mesh is incompatible with strong oxidizers. This is documented by the Sunoco MSDS[189] from April 13, 2005 which states in relevant part:

> 10. STABILITY AND REACTIVITY
>
> - **INCOMPATIBILITY**
> The following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid;

This warning is important because it states what the polypropylene in the TVT is incompatible with strong oxidizers like peroxides, which is particularly important because the vagina is a natural and ready source of peroxides. In fact, the vagina is a ready source of hydrogen peroxide production. In a paper titled, "The in vitro effects of hydrogen peroxide on vaginal microbial communities,"[190] the amount of hydrogen peroxide produced by the lactobacillus species is reported. The paper states, “Hydrogen Peroxide reached concentrations of from 0.05 to 1.0 mM, which under intensive aeration increases even up to 1.8 mM." This work confirmed the earlier research in the paper titled, "Hydrogen peroxide produced by Lactobacillus species as a regulatory molecule for vaginal micro-flora.[191] " The human body also contains other agents, such as hydrocarbons and various bacteria that impacts the MSDS discussed above and the warnings contained therein.[192]

The Prolene MSDS indicates that if you put the polypropylene used to make the TVT

[189] ETH.MESH.02026591 at 6591-6595.
[190] M Strus in FEMS Immunol Med Microbiol, 2006 October; 48(1:56-63).
[191] Med Dosw Microbiol. 2004:56(1):67-77.
[192] HB Moon, "Occurrence and accumulation patterns of polycyclic aromatic hydrocarbons and synthetic musk compounds in adipose tissues of Korean females" 2011; "Determination of volatile purgeable halogenated hydrocarbon in human adipose tissue and blood stream," from Bulletin of Environmental Contamination and Toxicology Volume 23 Issue 1 pp 244 – 249 published in 1979; Environmental Health Perspective’s, Vol. 60 pp. 127-131, Henry Anderson, "Utilization of Adipose Tissue Biopsy and Characterizing Human Halogenated Hydrocarbon Exposure", N. Das, Journal Biotechnology Research International 2010, Vol 2011, Article ID 941810 titled, "Review Article: Microbial Degradation of Petroleum Hydrocarbons Contaminant: An Overview”, "Health, Safety and Environment Fact Sheet: Hazardous Substances from CAW/TCA.” (www.caw.ca) August 2011, D. Lithner, 2011, entitled "Environmental and Health Hazards of Chemicals in Plastic Polymers and Products", University of Gothenburg.

mesh in an environment with peroxides, it will start to break down. Given the information available to Ethicon concerning the dangers of polypropylene coupled with the warnings and other contents of the MSDSs and related documents, at a minimum, Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene used in the TVT to alter inside a woman's pelvis (as well as other complications). If so, what materials are released into the body as a result, and what impact would those materials have on the body. The fact that the mesh in the TVT is susceptible to breaking down when in contact with peroxides makes it an unsuitable material to be placed in the vagina for the reasons discussed above. At the very least, Ethicon should have disclosed this information to physicians and patients considering use of their pelvic mesh.

Despite the warning in the MSDS for the polypropylene resin used to manufacture the TVT mesh cautioning against contact with strong oxidizers such as peroxides, there is no evidence that Ethicon tested the mesh to see if the peroxides in the vagina broke it down or informed surgeons about this important information contained in this or various other Manufacturer Safety Data Sheets (MSDS) regarding the use of polypropylene.

The fact that the MSDS for the TVT mesh warned against contact with strong oxidizers such as peroxides is information that a doctor would want to consider before implanting a permanent device in a woman's body for the rest of her life as substances in the vagina could cause the breakdown of the product, yet there Ethicon never informed doctors about the warning in the MSDS. As a result, Ethicon failed to act like a reasonable and prudent medical device manufacturer.

F. Ethicon's Prolene mesh is not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic;

Cytotoxicity means toxicity to the cells causing cell injury or death.[193] In a May 26, 2000, Ethicon Memo titled "Review of biocompatibility on the tension-free vaginal tape (TVT) system for compliance to FDA,"[194] the review contains a "Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device" from August 8, 1997.[195] The Cytotoxicity Assessment states "there is some evidence to suggest that the PP [polypropylene] mesh from the sterile Ulmsten device may have cytotoxic potential.[196] In addition, ISO Elution testing "resulted in marked cytotoxicity in tests conducted at Ethicon (Scotland)."

According to former Ethicon Medical Director, Dr. David Robinson, Ethicon never performed "a single long-term study . . . to determine whether or not the Ethicon mesh is clinically cytotoxic in women."[185] In addition, in its IFUs and Patient Brochures, Ethicon never informed physicians or their patients about the possibility of cytotoxicity.[197] Dr. Robinson testified that if there is a clinical related outcome related to cytotoxicity, it is reasonable for physicians to want to know that the mesh in the TVT product had been tested multiple times to be severely or marked cytotoxic.[198]

Cytotoxicity can cause death to cells that can lead to an inflammatory response leading to a multitude of injuries, including serious adverse complications such as erosions, chronic pelvic pain, recurrence, worsening incontinence, dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction or the need for additional surgeries. Ethicon did not undertake any long term testing to determine whether the marked cytotoxicity found in the TVT mesh had long term consequences for permanent human use.

[193] Robinson Dep. (9/11/13) 1091:11-21.
[194] ETH.MESH.06852118 at 2118-2129 (5/26/2000 Biocompatibility Review).
[195] ETH.MESH.06852120 (8/8/1997 Cytotoxicity Risk Assessment).
[196] *Id.* and Robinson Dep. 9/11/13) 1101:24-1102-5
[197] Robinson Dep. (9/11/13) 1114:15-18.
[198] Robinson Dep. (9/11/13) 1115:5-19.

This is true despite the fact that its own test results showed the mesh to by cytotoxic.

Because of the dangers and consequences that occur as a result of cytotoxicity, the fact that Ethicon had positive tests for cytotoxicity and did nothing to test for it makes the mesh in the TVT not suitable for permanent implantation. In addition, the potential for cytotoxicity or cell death is important information that physicians need to know in order to pass the information on to their patients so that an informed decision can be made about whether to have a permanent medical device implanted in their body. It is clear from Ethicon's Medical Director David Robinson that this information was never passed on to physicians despite the fact that it would have been reasonable for physicians to have this information. As a result, Ethicon did not act as a reasonably prudent medical device manufacturer in it failed to inform physicians and their patients about the risk of its mesh being cytotoxicity.

G. Ethicon's warnings and disclosures of adverse events in its TVT Instructions for Use ("IFU") are inadequate based on the adverse reactions and risks associated with the TVT that have been known to Ethicon from the time the TVT was first sold and marketed

The purpose of the IFU is for a medical device manufacturer to provide physicians with the information necessary for them to make decisions regarding the used a medical device for a particular patient. In addition, the IFU should disclose adverse reactions and risks known to the medical device manufacturer to the physician so that the risks can be relayed to the patient and an informed decision regarding the use of the product can be reached. Throughout my education, training, surgical and clinical practice, I have reviewed numerous IFUs for a variety of products, including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with a device. I have extensive clinical experience with IFUs and instructing patients about the adverse events/risks contained in the IFU. Similar to Medical Directors, Dr. Martin Weisberg and Dr. David

Robinson, I have gained expertise in IFUs through my extensive clinical experience reviewing IFUs, and consenting patients regarding IFUs, including Ethicon's own pelvic mesh products including the TVT line and Prolift.

Catherine Beath, Ethicon's former Vice President of Quality Assurance and Regulatory Affairs, testified that "physicians should be made aware of all the significant safety risks associated with the product in the IFU."[199] And, "a reasonably prudent medical device company would continually update the label consistent with developing data and information that becomes known to the company" when it is appropriate.[200] Similarly, former Medical Director Dr. David Robinson testified that the warnings and adverse event section of the IFU should include all significant risks and complications related to the procedure and the mesh.[201] According to Dr. Robinson, a device manufacturer must include this information because you want to make sure the doctors have all the information they need to adequately inform patients who are deciding to use the product.[202] According to Ethicon Medical Director Dr. Martin Weisberg, the goal of the IFU is to communicate the most important safety risks attributable to the TVT device and that an IFU should never exclude known hazards or complications.[203] Dr. Weisberg also believes that an IFU should not knowingly underestimate the risks of using the product.[204] And, if an IFU excludes known complications or understates the risks, it "fails in one of its principal purposes."[205] Finally, Peter Cecchini, a 43 year Ethicon employee and Regulatory Fellow and the person responsible for the TVT 510K, testified that the "regulatory standard for the IFU is the known risks are supposed to be included in the adverse reactions."[206] Mr. Cecchini testified that he relies on medical affairs to

[199] Beath Dep. (7/12/13) 592:7-11.
[200] Beath Dep. (7/11/13) 198: 8-13.
[201] Robinson Dep. (9/11/13) 238:12-25.
[202] Robinson Dep. (9/11/13) 239:1-11.
[203] Weisberg Dep. (8/9/13) 659:19-660:15.
[204] *Id*. at 960:13-16.
[205] *Id*. at 961:10-17.
[206] Cecchini,10/22/12, 65:5-12.

make sure he knows the known risks so they can be included in the IFU.[207]

1. <u>The TVT IFU Did Not Include All Known Risks, Was Inaccurate and Was Not Updated.</u>

a. The IFU did not include all known risks.

As noted above, Ethicon did not include the proper information concerning the dissection in the original IFU. There were also numerous other potential risks that were not included in the IFU at launch.

If you compare the adverse reactions/risks in the TVT IFUs to the adverse reactions/risks that were available and known to Ethicon at the time of the launch of TVT, it is clear that there are numerous adverse events absent from the IFU. From the time TVT was launched in the United States in December of 1998 to the present day, there have been ten versions of the Ethicon TVT IFU. These include the following versions: October, 1998, April, 1999, May 1999, September 8, 2000, December 22, 2003, February 11, 2005, April 7, 2006, October 13, 2008, November 29, 2010, and May, 2015 A chart showing the Adverse Reactions/Risks section for each version of the TVT Instructions for Use is set forth below.

[207] Cecchini, 10/22/12, 65:18-24.

Product	Production Prefix	Start Bates	End Bates	First Use Date	Last Use Date	Adverse Reactions / Risks
TVT	ETH.MESH	00203477	00203482	10/27/98 (U.S Launch IFU)	04/11/99	*Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation *As with all foreign bodies, PROLENE mesh may potentiate and existing infection. The Plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination *Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction
TVT	ETH.MESH	00204514	00204519	04/11/99	05/18/99	Same as 10/27/1998 IFU

TVT	ETH.MESH	00204562	00204593	05/18/99	09/08/00	* Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair. * Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation. * As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination. * Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.
TVT	ETH.MESH.	5225354	5225385	09/08/00	11/26/03	Same as 05/18/1999 IFU
TVT	ETH.MESH.	2340306	2340369	12/22/03	02/11/05	Same as 05/18/1999 IFU

TVT	ETH.MESH.	2340471	2340503	02/11/05	04/07/06	Same as 05/18/1999 IFU
TVT	ETH.MESH.	5222673	5222704	4/07/06	10/07/08	Same as 05/18/1999 IFU
TVT	ETH.MESH.	2340504	2340567	10/13/08	11/22/10	Same as 05/18/1999 IFU
TVT	ETH.MESH.	3427878	3427945	11/29/10	May, 2015	Same as 05/18/1999 IFU.
TVT	N/A	N/A	N/A	May, 2015	To Present Day	*Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra, or bowel, may occur and may require surgical repair. *Transitory local irritation at the wound site may occur. *As with any implant, a foreign body response may occur. This response could result in

						extrusion, erosion, exposure, fistula formation and/or inflammation. *Mesh extrusion, exposure, or erosion into the vagina or other structures or organs. *As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE mesh may potentiate an existing infection. *Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction. *Acute and/or chronic pain. *Voiding dysfunction. *Pain with intercourse which in some patients may not resolve. *Neuromuscular problems, including acute and/or chronic pain the groin, thigh, leg, pelvic and/or abdominal area may occur. *Recurrence of incontinence. *Bleeding including hemorrhage, or hematoma. *One or more revision surgeries may be necessary to treat these adverse reactions. *PROLENE mesh is a permanent implant that integrates into tissue, In cases in which the PROLENE mesh needs to be removed in part or whole, significant dissection may be required. *Seroma *Urge incontinence *Urinary frequency

						*Urinary Retention *Adhesion formation *Atypical vaginal discharge *Exposed mesh may cause pain or discomfort to the patient's partner during intercourse. *Death

In all six versions of the TVT IFU from May 19, 1999 to May of 2015, the Adverse Reactions/Risks section has remained exactly the same. It reads as follows:

> ADVERSE REACTIONS
>
> * Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
> * Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
> * As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
> * Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.[208]

Despite only listing the above adverse reactions/risks, it is clear from the testimony of Senior Ethicon Employees in both the Medical Affairs and Regulatory Affairs that every adverse reaction/risk that Ethicon has scientific knowledge of today, it had scientific knowledge about at the time the TVT was first sold in and certainly in 2004 when the first TVT was sold, marketed and launched. Medical Director, Piet Hinoul testified that Ethicon understood the following adverse events occurred from the time the TVT was first sold, years before the first TVT was sold:

[208] ETH.MESH.02340406.

Erosions through vaginal epithelium Infection
Pain
Urinary Problems
Erosions that could decrease patient's quality of life
Dyspareunia
Need for additional surgeries
Need for the removal of device
Urinary Tract Infections
Dysuria
DeNovo Urgency
Mesh Exposure
Fistula Formation
Hematoma
Abscess Formation
Narrowing of vaginal wall
Erosion which can occur any time in future
Contracture of mesh causing pain
Complications making it impossible to have sexual relations
Worsening Incontinence

Yet, none of these were in the TVT IFU at launch. There have been two significant updates to the Adverse events section of the TVT IFU since launch, one in May of 1999, and one in May of 2015. The May, 1999 updates to the IFU, including the addition to the Adverse Reactions section, were part of a corrective action plan taken by Ethicon due to a number of Serious Adverse Events being reported with the TVT device, 25 of which came to light in the two months prior to the IFU update. The majority of these Adverse events involved injury to vessels, bladder or bowel.[209] The Adverse Events section of the IFU was updated in May of 1999 to include the following:

- **Punctures of lacerations of vessels, nerves, bladder, or bowel may occur during needle passage and may require surgical repair.**

In addition to the updates to the Adverse Reactions section of the IFU, the Warnings and precautions section was updated to include the following statements:

[209] ETH.MESH.07424335.

- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks.
- Retropubic bleeding may occur postoperatively. Observe for symptoms or signs before releasing patient from hospital.

The May, 2015 IFU included a large number of significant updates, including warnings about pain, chronic pain, dyspareunia for the patient and/or her partner, need for multiple surgeries, and the difficulty in removing all or part of the device. These adverse events, which were added to the TVT IFU in May of 1999 and May of 2015, are all risks that Ethicon knew of at the time of launch of the TVT, and should have been included in the IFU since launch.

In addition, as discussed more fully throughout this report, Ethicon failed to include significant risks in its IFU related to the Prolene polypropylene mesh, including potential cytotoxicity, association with tumor formations and that the mesh can degrade, shrink and contract. The IFU also fails to include risks associated with the Prolene mesh, including chronic foreign body reaction, fibrotic bridging, infections/biofilms, fraying/particle loss and roping/curling of the mechanically cut mesh. Ethicon also failed to include that the laser cut mesh is three times stiffer than the mechanically cut mesh and that there are significant risks of erosions, pain, dyspareunia and urinary dysfunction associated with stiff, rigid meshes in the TVT-O manufactured with the laser cut mesh.

Moreover, the IFU fails to inform physicians that patients may require multiple surgeries to treat erosions, that erosions could be severe and untreatable, that patients could endure lifelong severe pain or dyspareunia/painful sex, removing the mesh and revision surgeries can be complicated and challenging for both the patient and physician, and complete removal of the TVT mesh is likely impossible.

Medical Director Dr. Weisberg testified that Ethicon did not include: “permanent,

lifelong, worsening and debilitating pain", lifelong risk of surgical repairs for erosions, "severe or chronic inflammation", collapse under strain and cause fibrotic bridging, that the product can degrade, that polypropylene is cytotoxic, severe erosion, or particle loss.[210]

But Ethicon did not disclose this information to physicians in its IFUs regarding characteristics of the old construction mesh in TVT, including that it is small pore, heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh, and that it deforms and the pores collapse with tension. In fact, Ethicon medical director Piet Hinoul testified if Ethicon did warn that roping, curling and particle loss can cause pain and erosions Ethicon would have to take the mesh off the market.[211]

Moreover, the IFU failed to inform physicians of the frequency, duration and severity of the risks associated with the TVT device until the May, 2015 IFU update. In addition, former Medical Director, Dr. David Robinson, testified that Ethicon never informed physicians that patients may require multiple surgeries to treat erosions, that erosions could be severe and untreatable, and that patients could endure lifelong severe pain or dyspareunia/painful sex. This is true despite, as discussed above, Ethicon had scientific knowledge of the risks at the time of launch.

b. The IFU inaccurately portrayed risks.

In addition to excluding certain known risks, Ethicon significantly downplayed the risks that it actually listed in its IFU. This is especially true with respect to erosions. On the topic of erosions, in the Adverse Event/Risks section in the TVT IFU, in place from the time of launch until present day, it states:

Transitory local irritation at the wound site and a transitory foreign body

[210] Weisberg Dep. (8/9/13) 968:12-972:21.
[211] Trial testimony of Piet Hinoul, Batiste v. Ethicon, page 67.

> response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.

This language significantly downplays the permanent nature of erosions and suggests to physicians that erosions are a "transitory" or temporary problem. As shown in an email exchange between Ethicon's Associate Medical Director of Worldwide Customer Quality Meng Chen, M.D., Ph.D and Bryan Lisa in the Regulatory Affairs Department, it was clear that the adverse events were not "transitory." Chen wrote, "Pardon me again, from what I see each day, these patient experiences are not "transitory" at all."[212]

Ethicon also had scientific evidence that erosions could occur many years after implantation of the device. In Minutes from June 22, 2001 Scientific Advisory Committee on Pelvic Floor Repair, it was a "Consensus: Erosion is a risk. Erosion, possibly an infection response. Typically seen by 3 mos, usually by 6-12 mos. Can present late, 3 years. To vagina- not a good situation. To bladder, urethra or rectum-a very bad situation."[213] "There have been reports of erosions into the urethra that are not picked up until months even years after the procedure."[214] In October 2002, Medical Director Dr. Martin Weisberg was involved in email exchange with European Science Director Axel Arnaud about downplaying risks with respect to erosions. Specifically, Dr. Arnaud suggested to Dr. Weisberg that Ethicon needed "to be more elusive" when discussing potential complications like erosions.[215]

According to Medical Director Dr. Martin Weisberg and former Medical Director Dr. David Robinson, Ethicon never disclosed or warned doctors or patients in IFUs or Patient Brochures that the use of TVT slings can cause lifelong risk of erosions.[216] Despite the fact Ethicon had scientific feedback from one of its own doctors that experiences were not

[212] ETH.MESH.04093125 (1/29/09 Email between Meng Chen and Bryan Lisa).
[213] ETH.MESH.02089392.
[214] ETH.MESH.04099233 (September 24, 2008 email fromMelissa Day to Meng Chen and others).
[215] ETH.MESH.03910175-03910177.
[216] Weisberg dep. (8/9/13) 968:2-969:10; Robinson Dep. (9/11/13) 329:12-330:7.

transitory and that she had concerns about the IFU and the transitory language, Ethicon never informed physicians or disclosed it in its IFU.

c. Ethicon failed to update the IFU.

Once TVT was on the market, Ethicon refused to appropriately update the IFU to reflect the known risks above and additional risks. On December 19, 2008, after Dr. Meng Chen had received a complaint from a number of patients about not being fully informed of the risks of the procedure, she recommended to senior management that the IFU be updated:

> [The patient] was given the most accurate consent for the potential adverse reaction known in 2005. However, we are in 2008 now, and there are two more TVT family products (TVTO and TVTS) on the market. Our post-market knowledge with these products are much more than what we have in the IFUs of all three types of TVTs (TVT-Abdominal, Obturator and Secur). My reason for bringing this point to you is maybe you may look into it from senior management perspective and to facilitate the IFU update for all three TVTs, particularly in the area of 'Potential Adverse Reactions'…. One of the paths for a better pre- operative consent is to provide an updated IFU to the operating physicians that reflecting the current knowledge of the manufacturer's on the potential adverse reactions."[217]

In a January 29, 2009 email, Meng Chen wrote again that the IFU should be updated to make it clear that the irritation and foreign body response were a result of the tape itself and that this "could result in tape extrusion, tape erosion, fistula formation or inflammation."[218] When working on the Mini-O/Abbrevo IFU, Ethicon employees noted that the older IFU's should be updated. Dr. Aaron Kirkemo wrote:

> I would agree from the meeting today that now that we have 12+ years of experience with TVT classic that learnings from the field would probably drive a relook at the TVT Classic IFU as reflected by some of your comments in this document."[219]

In response, Dr. Robison asked: "has there been agreement re: a project to revise TVT and

[217] ETH.MESH.04092868.
[218] ETH.MESH.04094863 (e-mail from Dr. Meng Chen to Bryan Lisa, Jan. 29, 2009).
[219] ETH.MESH.01239065 at 9066 (July 14, 2009 email from Aaron Kirkemo MD to Piet Hinoul MD and David Robinson MD).

TVTO?"[220] There was indeed agreement at upper management – there would be no revision to incorporate what they had learned: "Per Scott C and Stale, they just want to "look forward" with this project. Their plans are to leave TVT Classic [and TVT] as is. Aaron."[221]

Interestingly, in 2008, 2011, 2012, and 2015 Ethicon added numerous adverse reactions and risks to its Patient Brochures that have never been disclosed in previous versions of the Patient Brochures. Some of these adverse reactions and risk have never been disclosed in the TVT IFUs even at present time, and all of these were not in TVT IFUs prior to May, 2015 These risks are as follows:

From Patient Brochures (never in IFU prior to May, 2015. Those in Yellow are still not in IFU)
2008
Difficulty urinating Pain
Scarring
Mesh Exposure requiring treatment
2011
Mesh exposure into the vaginal canal
Mesh exposure associated with pain during intercourse for the patient and partner
Mesh exposure which may require removal of exposed mesh in office or operating room
2012
Pelvic Pain
Development of Urinary Incontinence
Voiding Difficulties
Hemorrhage or hematoma
Urinary tract infection Wound healing problems Injury to ureters
Pelvic abscess formation
Risk of infection
Vaginal scarring
Mesh contracture (mesh shortening due to scar tissue)
2015
Anesthesia risks
Pain (temporary or chronic)
Seroma
Neuro-muscular problems (including pain in the groin, thigh, leg, pelvic or abdominal area
Adhesion formation

[220] *Id.*
[221] *Id.*

Abnormal vaginal discharge
Recurrent incontinence
Death
These complications may require additional medical treatment, hospitalization, or surgery
These complications may resolve over time or may be chronic
There is also a risk that the mesh material may erode into another organ such as the bladder or urethra (mesh erosion) and cause pain and additional problems. Mesh erosion would likely require additional surgery to remove the mesh from the organ.

Some of these risks have been disclosed in Ethicon's other PROLENE mesh IFUs. For example, Ethicon's IFU for PROLENE hernia mesh states as follows: "The use of PROLENE Mesh in contaminated wounds should be with the understanding that subsequent infection may require removal of the material."[222] Even though Ethicon changed its Patient Brochures in 2011 and 2012 to include additional significant adverse events/risks, it never added the same information to the TVT IFU until May of 2015. This is true despite the fact that Ethicon had internal discussions about updating the IFU in 2009 after the 2008 FDA Public Health Notification (PHN). Specifically, a meeting was held to decide, among other issues, whether to update "the current Adverse Reaction of tape exposure and post-operative dyspareunia in the TVT-family products…."[223]

After discussing the 2008 PHN, competitors' labels and Remetrex issues, impressions were that tape exposure/erosion/extrusion were very frequently reported, patients did not feel there were adequate pre-op consent or risk-benefit assessment, patient specific concerns about exposure/erosion/extrusion, incontinence recurrence, post-operative dyspareunia and pain-affect quality of live and affect daily routine, re-operations and post-operative complications disproportionate to pre-operative-consent-expectations.[224] Despite these discussions and Ethicon's scientific knowledge of these serious, devastating and life-changing adverse

[222] ETH.MESH.02342102.
[223] ETH.MESH 04081189.
[224] *Id.*

events/risks, to this day, it has never updated or changed its IFU to include this information.

Repeatedly, the reason given for not updating an IFU to make it more accurate and safer was that doing so would threaten the launch timing of a new product. For example, when discussing the IFU for TVT-Exact, Dr. David Robinson cautioned against making too many changes from the original TVT-R IFU: "Just to clarify… the more changes we make to the IFU that differ from TVT-Classic, the higher the risk will be to the submission timing."[225]

In summary, Ethicon did not fully inform physicians about numerous adverse reactions/risks associated with the TVT despite the fact that Ethicon had scientific knowledge of the risks from the time the product was first sold. As a result, physicians were unable to fully consent and inform patients of the risk associated with TVT. In addition, some risks included by Ethicon in the IFU are mischaracterized to minimize the actual risk. Finally, when given numerous opportunities to update the IFU, and in the face of specific requests to do so from numerous medical professionals, Ethicon did not make the necessary updates. To a reasonable degree of medical certainty, this prevented physicians and patients the ability to make an informed choice regarding the use of the TVT. For a surgeon to properly inform the patient of all the known risks involved in any procedure involving an implantable medical device, the surgeon relies upon the manufacturer to have scientific knowledge of and convey all characteristics of its products that could impact safety and efficacy. Specifically, surgeons rely on the "Adverse Events/Risks" section of a medical device IFU to gain scientific knowledge regarding adverse events or undesirable effects that the company knows are associated with the product.

[225] ETH.MESH.10632650 at 10632652.

D. The TVT Device Is Not Designed for Special Patient Populations Nor Does the IFU or Marketing Inform Physicians or These Patients of Poorer Outcomes or Higher Risks.

Ethicon promoted the TVT as a "reproducible" technique that was appropriate for all patients. For example, Ethicon instructed its sales force to specifically target physicians to use the TVT and TVT in obese patients.[226] However, as Ethicon's Medical Director, Dr. Kirkemo, testified obese patients do not fare well with these devices.

> Q. One of the things that was actually shown in the TVT World study that you worked on was that for obese patients, for example, the efficacy was significantly down when slings were used in obese patients; is that correct?
> A. Obese people tend -- not to do as well.

In fact, Ethicon's study showed obese patients had about one half the success of those patients who were not obese. In addition, as Dr. Kirkemo testified, obese women suffered from more complications: "Their chance of success goes down. Their risk of complications goes up."[227]

Yet, Ethicon did not put this critical information into the IFU. Dr. Kirkemo testified:

> Q. Did you ever put that in the IFU?
> A. No….[228]

Not only did Ethicon not put this critical information in the IFU, Ethicon also did not inform patients:

> Q. Did you ever tell patients that in a single patient brochure, that if they were obese, their chances of this being successful were less than half?
> A. We did not.[229]

Ethicon also did not include information in its IFU about how the TVT had less efficacy and higher risk for older women or younger, active women.

> Q. Did you -- you also learned in the TVT World study, or maybe you knew this before, too, that being elderly decreased, or being very young, in fact, decreased the efficacy of the Ethicon sling procedures; correct?

[226] See, e.g., ETH.MESH.00640394 (trying to convince physicians to use TVT on obese patients); ETH.MESH.05119622 at 9623 (TVT "is a good choice for the obese patient or elderly patient….").
[227] Kirkemo Dep. (1/7/2014) 556:24-557:1.
[228] Kirkemo Dep. (1/7/2014) 556:4-19.
[229] Kirkemo Dep. (1/7/2014) 557:5-557:9.

A. With any incontinence operation, old people tend not to, you know, do as well.
Q. And was that ever put in a patient brochure or communicated to patients as far as you know?
A. As near as I can tell, in any marketing document, no.
Q. And what about the very young or the younger women; that was shown in TVT World that even younger women had lower efficacy; correct?
A. Some women that are very, very active can -- and have ISD can overcome the effect of the sling.
Q. In other words, the sling can fail.
A. The sling can be less than a hundred percent effective.
Q. And that was never actually communicated to patients as far as you know, correct, by Ethicon?
A: To my knowledge, no.
Q. And neither the older women or the younger women in issue we were just talking about, neither of those are included in the IFU; correct?
A: Those specific things are not mentioned.[230]

Ethicon also did not inform physicians and patients that the TVT devices, including the TVT would not work as well and would be more dangerous for women who smoked or who had Diabetes – a very large percentage of the patients to whom TVT was being marketed:

Q. Smoking decreases the efficacy of slings; correct?
A. Yes.
Q. Diabetes decreases the efficacy of slings; correct?
A. It can because you have neurologic, you know, disease.
Q. Neither smoking nor diabetes is listed as a potential contraindication or something special to look for in the IFU; correct?
A. It is not listed in the IFU….
Q. And Ethicon never communicated to patients that smoking would increase their risk of adverse outcomes or decrease the chance that the sling would work; correct?
A. We did not.
Q. And the same with diabetes. Ethicon never communicated to patients when they were selling TVT devices that diabetes would decrease the chance that the device would work or increase the chance that they would have an adverse event; correct?
A. I did not see that, no.

Ethicon knew that there were other patient populations that also faced increased risk or lower success rates with the TVT. Specifically, Ethicon knew that women who had prior pelvic surgery, prior pelvic injury or an infection, could be at increased risk if undergoing the

[230] Kirkemo Dep. (1/7/2014) 557:10-558:21.

TVT surgery. In 1999, Ethicon discussed putting another warning in the TVT IFU related to patients who had previous surgeries because of scar tissue.[231] The proposed warning was "patients who have had previous surgical procedures may require special consideration due to scar tissue."[232] Ethicon was concerned that the risk of mesh extrusion was increased in women with postoperative infection, previous vaginal surgery, vaginal atrophy or vaginal injury.[233] Dr. Isenberg, Ethicon medical director, admitted that if Ethicon knew this, it would have been reasonable to include a warning and, further, physicians and their patients would want to know this information. However, Ethicon was "under extreme pressure" to finish the IFU to meet a scheduled launch date in 1999, so did not include the statement in the April, 1999 IFU update.[234] Ethicon planned to discuss the issue for possible inclusion in the IFU in the future, but I have seen no evidence of such discussion, and this warning never made it into the IFU. Again, despite these discussions in 1999 and former Medical Director Dr. Isenberg's opinions that it would be reasonable to have this information in the IFU, to this day, this critical information remains absent from the IFU.

Finally, Ethicon also knew that the method of anesthesia utilized during the TVT surgery could affect patients' outcomes, but didn't disclose that information to physicians or patients. Ethicon's internal documents, including interviews with Ethicon's key opinion leader, Dr. Carl Nilsson, Ethicon U.S. Marketing Research documents, and letters from the inventor of the TVT (Dr. Ulmsten) show that Ethicon knew that performing the TVT procedure under general anesthesia as opposed to local anesthesia decreased the chance for success of the surgery and also increased a patient's risk of urinary retention and erosions.[235] This is further supported by the testimony of Dr. Richard Isenberg, a former medical director for Ethicon, who was at

[231] ETH.MESH.08505071, ETH.MESH.00203456, Eth.Mesh.00159634-00159719 at 00159697.
[232] ETH.MESH.08505291.
[233] *Id.*
[234] ETH.MESH.00203456.
[235] Eth.Mesh.04048515-04048520; Eth.Mesh.00130934-00130941, Eth.Mesh. 00400954-00400956.

Ethicon just after the initial launch of the TVT.[236] Dr. Isenberg testified that the IFU could be better worded so that physicians knew that local anesthesia should be preferred over general anesthesia.[237] In addition, according to Dr. Isenberg, Dr. Ulmsten, inventor of the product, informed Ethicon that the TVT procedure should be carried out under local anesthesia unless it was a special situation.[238] Despite the inventor's desire to have this language listed, to this day, it does not appear in the IFU.[239] Dr. Isenberg was also aware that using general anesthesia could cause the success rate of the procedure to go down and put the patient at increased risk for urinary retention and erosions.[240] He testified that he believes a responsible company should have put this information in the IFU because the IFU is the one document that you can count on every physician receiving.[241] I agree. Again, however, to this day, this warning does not appear in the TVT IFU.

The TVT is dangerous and can cause significant, lifelong injury to women, due in part to its "one-size fits all" design. Ethicon failed to inform physicians that there are certain patient populations that face greater risks and less success with the TVT. Ethicon needed to pass this critical information on to physicians in the IFU so that they could have an appropriate informed consent discussion with their patients.

Accordingly, it is my opinion to a reasonable degree of medical certainty that the TVT as designed is not effective for special patient populations. In addition, the TVT is dangerous and can cause significant, lifelong injury due in part to its "one-size fits all" design. Moreover, Ethicon failed to inform physicians of the importance of these patient variations and the potential for permanent, serious injury from the TVT. Because Ethicon failed to inform

[236] Isenberg, 11/6/13, 461:16-530:13.
[237] Id. at 526:25-528-18.
[238] Id. at 553:15-554:21.
[239] *Id.*
[240] Id. at 566:9-15.
[241] Id. at 566:3-8.

physicians, Ethicon also removed the ability of the physicians to fully inform patients of these risks.

E. Ethicon failed to reveal material facts about complications and conflict of interests regarding data promoted in the materials.

Since the TVT was first launched, Ethicon has sent materials in various forms to physicians promoting long term follow up data on the original cohort of patients implanted with the TVT from 1995-1996.[242] Ethicon continued to cite to this data in its TVT materials.[243] In addition, the materials tout low complication rates related to various adverse reactions, including erosions. These materials include press releases, marketing brochures and email blasts.

The long term data primarily relied on by Ethicon throughout these materials relates to the Ulmsten/Nillson studies. These studies were originally started by Dr. Ulmsten, the inventor of the TVT, and continued by Dr. Nillson after Dr. Ulmsten's death. Prior to selling the TVT to Johnson & Johnson, Dr. Ulmsten owned a company called Medscand. As discussed more fully below, Johnson & Johnson hired Dr. Ulmsten and Medscand to conduct studies related to the TVT. To this day, Ethicon relies heavily on these studies and uses them in numerous promotional materials despite the fact that Ethicon never disclosed to physicians the potential conflict of interest and inherent bias that exists due to Dr. Ulmsten's relationship with Ethicon and Johnson & Johnson. In addition, Ethicon never disclosed to physicians that the device used in the original Medscand study was different than the TVT device. It is important to physicians using the TVT that the data in these types of promotional materials is accurate, unbiased and that physicians are informed about any potential conflicts of interest in the data contained within the materials. In other words, physicians rely on Ethicon to provide fair and balanced

[242] ETH.MESH.0015598, ETH.MESH.00658058, ETH.MESH.01186068, ETH.MESH.02236784, ETH.MESH.02237103, ETH.MESH.03459211, ETH.MESH.05183409, ETH.MESH.00339437; ETH.MESH.05794787.
[243] ETH.MESH.00163582.

information and to ensure that physician have been given all the data and not just the positive press release data.

Despite using the Ulmsten data to promote the TVT, Ethicon never disclosed to physicians the bias and inherent conflict of interest related to the Ulmsten data. Specifically, in its promotional materials, Ethicon (Johnson and Johnson) never informed physicians about its relationship and contracts with Professor Ulmsten and his company Medscand. It is clear from the contracts that the publications and data from Dr. Ulmsten where contracted for hire by Johnson and Johnson International.[244]

The License and Supply Agreement between Johnson and Johnson International and Medscand (Ulmsten's Company) dated February 13, 1997, states in section 3.6 Milestone Payments:

> Johnson and Johnson International (JJI) shall pay shall pay to Medscand the following payments (b). A payment in the amount of $400,000.00 due on February 28, 1997; provided, however, that in the event that Clinical Trials as specified in Exhibit C have not been completed by such date, then such amount shall not be due until the completion of the Clinical Trials.[245]

Under Exhibit F, Consulting Agreement with Professor Alf Ivar Ulmsten, section 4 Confidential Information Rights to Inventions and Copyrights (B) it states:

> Any copyrightable work whether published or unpublished created by supplier Dr. Ulmsten directly as a result of or during the performance of services herein shall be considered a work made for hire, to the fullest extent permitted by law and all rights, titles and interest herein, including worldwide copyrights shall be the property of the company as the employer and party specially commissioned said work.[246]

Finally, in Exhibit C, Clinical Trials, it states:

> The results of clinical trials will be considered acceptable if, first, they do not differ significantly from the results published in the original article published in the Int. Urogynecol J 1996-7:81-86 by U. Ulmsten, et.al., with regards to the

[244] ETH.MESH.08696085 at 085-6134.
[245] ETH.MESH.08696091.
[246] ETH.MESH.0869116.

> following items: Safety 1.1, preoperative complications 1.2 , post operative complications 1 year from operation 2. Efficacy. Second Long term results over 1 year from operation do not show a deterioration of rates significantly different from those of the standard suburethral slingplasties. It is assumed that from 12 – 60 months a gradual decrease in efficacy of 5% is normal. 3. No significant numbers of unexpected i.e. not addressed in the original article published in the Int. Urogynecol J 19967 81-86 by U.Ulmsten at et.al. procedure related i.e. not addressed in the review article published in the Int. Urogynecol J 19945: 228-239 by G. N. Ghomiem et.al. complications appear at any time in the postoperative course.[247]

In total, Dr. Ulmsten stood to gain millions of dollars for the 6 papers that he published on the TVT device. In addition, the results of those studies would be found acceptable for payment only if they did not differ from the parameters sent by Johnson & Johnson regarding complications and efficacy. The Ulmsten studies have an inherent conflict of interest and bias as they were "made for hire" and standards were set by Johnson & Johnson. As set forth above, if Dr. Ulmsten did not meet the standards set forth by Johnson & Johnson, he did not receive substantial payments for the "studies." As a result of this relationship, there is a clear conflict of interest and potential for enormous bias issues.

The conflict of interest and bias created by the relationship between Ethicon and Dr. Ulmsten was acknowledged by Dr. Axel Arnaud, Ethicon's European Medical Director, in a recent deposition. Specifically, Dr. Arnaud testified that such an agreement like the one discussed above between Dr. Ulmsten and Johnson & Johnson creates a potential conflict of interest.[248] Dr. Arnaud also acknowledged that when Johnson & Johnson enters into this type of agreement with a physician or his company and the study is published, there "certainly" needs to be a disclosure of the relationship.[249] Additionally, Former Ethicon Medical Director, Dr. David Robinson, testified that in his experience working in the industry for medical device

[247] ETH.MESH.08696132.
[248] Arnaud Dep. (7/20/13) 497:24-501:21, 509:8-17.
[249] Arnaud Dep. (7/20/13) 514:17-515:1.

manufacturers, it is best that potential biases be disclosed.[250] He also testified that if publications from somebody like Ulmsten or Nilsson about safety and efficacy are being published, it is best if they disclose that they have a financial bias or conflict of interest.[251] In fact, in an April 2009 email exchange with Medical Director Piet Hinoul about a physician who, like Ulmsten, is a consultant and inventor for competitor Boston Scientific, Dr. Robinson states that that situation presents "enormous bias issues."[252] Despite two of its medical directors testifying that the relationship between Ulmsten and carried over to Nilsson presents a conflict of interest and bias, Ethicon has never disclosed this information in its promotional pieces. This is information physicians and patients have a right to know so that a proper informed decision regarding the value of the data in the studies and the use of the product can be made.

Aside from never disclosing to physicians the underlying conflict of interest and bias of the Ulmsten studies in its promotional pieces, Ethicon also never informed them about other problems with the data, including incomplete data on the original cohort, data incorrectly reported and erosion rates underreported. In the original 510k submission for TVT Classic, Ethicon used Medscand data from the Scandinavian Multicenter Study.[253] The report shows that 12 month follow was obtained for 90 of the original 131 patients, without explanation of why there was a loss of 41 patients from the study. The study also describes a complication of wound infection: "while the vaginal infection required surgical intervention with resection of exposed mesh." This represents a vaginal mesh erosion/extrusion/ exposure and needs to be reported as such. However, when the paper was published (Ulmsten, Int Urogynecol J 1998), the paper states that there was no defect healing and no tape rejections. It further misrepresents

[250] Robinson Dep. (9/11/13) 214:15-21.
[251] Robinson Dep. (9/11/12) 215:8-13.
[252] ETH.MESH.03259439; Robinson Dep. (9/11/13) 219:6-220:10.
[253] ETH.MESH 00371587.

the outcome for this patient as "The patient with the wound infection had vaginal atrophy. After minimal vaginal wall resection and effective local estrogen treatment she healed without further intervention. There was no tape rejection."

If Ulmsten had reported a mesh erosion/extrusion/exposure with mesh excision in his study, it would not have been acceptable under Exhibit C of his consulting contract for payment of the $400,000.[254] This demonstrates that the results of this paper were potentially biased by the payment Ulmsten would receive for favorable data and should discount the data. At the very least, Ethicon should have informed physicians about the relationship between Ethicon and the Ulmsten studies.

Many of the marketing brochures tout the "[t]he urethral erosion rate less than or equal to that of traditional slings; no reported urethral erosions in 10 studies of 50+ patients."[255] The reference used for the first part of this statement is from Dr. Gary Leach) who looked at traditional sling procedures done before 1993, when traditional slings were performed at the bladder neck and purposely placed under tension to treat severe stress urinary incontinence from intrinsic sphincter deficiency (particularly among Urogynecologists).

The second part of this statement regarding "no uretheral erosions" is incorrect. In published studies, Dr. Karram found one case of urethral erosion in his study of 350 Gynecare TVTs performed (Karram Obstet Gynecol 2003) and Hammad found nine cases of urethral erosion in his study (Hammad Eur Urol 2005).[256] His study followed the complications of 1459 patients 993 of whom had Gynecare TVT, while the remainder has SPARC procedures. While the authors do not break down the incidence of urethral erosion by product, it is exceedingly unlikely that all erosions happen in the SPARC group.

[254] ETH.MESH 08696132.
[255] ETH.MESH 00339439.
[256] Karram, M.M., et al., *Complications and untoward effects of the tension-free vaginal tape procedure*, Ob & Gyn 2003, 101:929-32.

The statement regarding "no uretheral erosions" also did not include deTayrac's 2003 paper of 61 patients (31 TVTs) which showed a 3% urethral erosion rate.[257] Dr. Shlomo Raz described a study of 26 patients who presented with voiding dysfunction, including symptoms of severe urethral, pelvic and genital pain, urinary retention, recurrent UTIs, de-novo urgency with urge incontinence found to have mesh from a sling procedure in the bladder or urethra.[258] Their patients were found to have been treated conservatively with anticholinergic medication. They conclude that "dysfunctional voiding symptoms after sling procedure should elicit a high degree of suspicion if pharmacotherapy is not successful in alleviating symptoms...Cystoscopy should be considered if the patient remains symptomatic despite pharmacotherapy."

In one of the Nilsson studies, Dr. Nilsson describes four patients on "anticolinergics" (Int Urogynecol J 2008 Table 3). They conclude: "It is also encouraging to see that no late adverse effects of the polypropylene tape material was found and that erosion of the tape into adjacent tissue did not occur." However, this statement cannot be made for 4 patients who are on pharmacotherapy without a cystoscopy, which was not performed in the 11 year follow-up study. Dr. Raz's review of the literature found multiple cases of urethral erosions in a large series with TVT.[259] There have also been multiple case reports attesting to the fact that urethral erosion does occur specifically with Gynecare TVT products.[260] To imply that urethral erosion does not occur is not giving physicians fair and balanced information about the true incidence of urethral erosions with TVT products.

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[257] de Tayrac, R., et al, *A prospective randomized trial comparing tension-free vaginal tape for surgical treatment of stress urinary incontinence*, Am J Obstet Gynecol 2004, 190:602-8.
[258] Deng D.Y., et al., *Presentation and management of major complications of midurethral slings: Are complications under reported*, Neurourology Urodynamics 2007, 26:46-52.
[259] Karram 2003, Hammad 2005.
[260] Sweat, S., et al, *Polypropylene Mesh Tape for Stress Urinary Incontinence: Complication of Urethral Erosion and Outlet Obstruction*, J Urology 2002, 168:144-146; Gerstenbluth, R.E., et al, *Simultaneous Urethral Erosion of Tension-Free Vaginal Tape and Woven Polyester Pubovaginal Sling*, J Urol. 2003, (2 Pt 1) 170:525-6; Vassallo, B.J.., et al., *Management of latrogenic Vaginal Constriction*, Am J Obstet Gynecol 2003, 102(3):512-20; Haferkamp, A., et al., *Urethral Erosion of Tension-Free Vaginal Tape*, J Urol 2002, 167(1): 250.

Later, Nilsson publishes the 5 year follow-up of this cohort.[261] He describes the cohort: "a prospective open multicenter trial was conducted in the Nordic countries at the beginning of 1995. The short-term results were published in 1998." This implies that these are the same patients as published in 1998. It is interesting or an incredible coincidence that the exact number of patients receiving 12 months of follow-up in the Medscand publication (90) was the exact number being described in the 5 year study. There is again no mention of the outcome of the other 41 patients from the original cohort. Another interesting detail in the 5 year study is that the original number of centers used for the study (6) was now down to 3, again without explanation. The 5 year report does describe the original patient with the wound infection but again fails to mention she had mesh excised, "1 case (1.1%) of infection of operating site was observed."

In 2006, Dr. Nilsson published a different study on long term outcome of patients with TVT.[262] He describes his new patient population: "A multi-center study comprising only carefully selected primary cases revealed a promising cure rate of 85% after 5 years (reference his 5 year study) and 81% at 7 years."[263] These two papers are the subject of many press releases and marketing brochures, but they never described that these were carefully selected patients. "To our knowledge, the long-term effect and effectiveness of the TVT procedure has not yet been studied in an unselected patient group. We earlier reported 16-month follow-up results of a general patient group referred to a tertiary medical unit and comprising primary, recurrent, mixed, and low pressure urethra cases. In the present study, we report the long-term results in the same above-mentioned group." They describe a 3.1% mesh "visualized" rate, half of which needed surgical resection. These results, more representative of what one would see

[261] Ulmsten data; Nilsson, Int Urogynecol J 2001.
[262] Kuuva , N., et al., *Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women*, Acta Obstetricia Gynecologica Scandanavica 2006, 85:4 482-87.
[263] Nilsson, Obstet Gynecol 2004.

in a normal practice, is never mentioned in press releases or marketing documents.

Conversely, when Ethicon receives adverse information, it does not make it into the promotional pieces. Dr. AC Wang's abstract, "Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report" was used in the original 510k submission in October of 1997 as support for FDA clearance of the TVT.[264] However, when Dr. Wang reported that he had 25 cases of "failure of vaginal healing considered by him to be potential tape rejection...in each case the revision failed within 2 weeks, requiring further surgery to excise mesh and repair the vaginal wound," this important information never made it into the marketing materials or press releases.[265]

The long-term follow-up data (Ulmsten/Nillson data) used by Ethicon to promote the lack of risk of TVT is spurious at best. We have incomplete data on the original cohort, data that is falsely reported, original sites that were excluded without explanation and a lead investigator who had a significant relationship and financial incentive to reach certain results with the data. This is the same data which is now used repeatedly in promotional and marketing materials sent to physicians.

K. The Benefits of the TVT are Outweighed by the Severe, Debilitating and Life Changing Complications Associated with TVT

It is my opinion, based on my training, experience and extensive review of the literature and Ethicon's internal documents that the benefits of the TVT are outweighed by the severe, debilitating and life changing complications associated with the medical device. It is clear that a substantial number of women who are implanted with the TVT have already and will continue to suffer chronic, debilitating erosions or pain, among other complications, and these life changing complications outweigh the benefits of the TVT, a device used to treat a quality

[264] ETH.MESH.00371551.
[265] ETH.MESH.00409675.

of life issue.

This is especially true given that traditional surgeries like the Burch and pubovaginal slings are not associated with the frequency or extent of these life changing complications. The efficacy of the TVT is equivalent to the traditional surgeries like the Burch. Traditional surgeries are not associated with TVT mesh based complications like contraction and erosion, however, with clinically significant erosion. And, further, although traditional surgeries can cause symptoms such as pain following surgery, including dyspareunia, the risk, duration, extent and severity of chronic pain including dyspareunia following the TVT is much greater than with traditional surgeries, and of course those surgeries do not result in the often untreatable complications and symptoms that result from the TVT mesh.

There were reasonably feasible safer alternatives available to Ethicon for the treatment of patients in this case. For example, the Burch procedure would have been an appropriate treatment for the stress urinary incontinence. The Burch procedure eliminates the risks specifically associated with the old construction heavyweight mesh used in the TVT because the Burch procedure does not require the use of mesh. Another feasible safer alternative to the TVT would have included autologous fascia slings. Sutures used in an alternative design to the TVT (i.e., Burch); an autologous fascial sling; or, an allograft sling (i.e., Repliform) would have been a safer alternative design to the TVT.

Moreover, because of the manufacturing defect present in the mechanical cut mesh and laser cut mesh, several additional feasible alternatives were available to Ethicon that would have been less dangerous. As I have testified in previous cases where women have suffered permanent debilitating injuries from TVT mesh products, these alternatives depend on the patient, patient's lifestyle, patient's medical history, and the injuries the patient suffers from. When patients are young and active at the time of surgery, and when the mesh

contains a manufacturing defect making the mechanical cut mesh especially prone to losing particles, fraying and deformation and because of injuries and risks from the TVT device, certain lighter weight, larger pore mesh resistant to fraying, deformation, shrinkage and particle loss both by design and by improved manufacturing, and include a less invasive implantation method than that used with the TVT would have been less dangerous and a feasible alternative. When the mesh contains a manufacturing defect making the laser cut mesh especially prone to stiffness and rigidity, and because of injuries and risks from the TVT device, certain lighter weight, larger pore mesh resistant to excessive stiffness and rigidity both by design and by improved manufacturing, and include a less invasive implantation method than that used with the TVT would have been less dangerous and a feasible alternative.

In addition, based on Ethicon's internal documents, deposition testimony, and the medical literature, feasible alternatives would have included individually or collectively a lighter weight, larger pore mesh material. Indeed, Ethicon had lighter weight larger pore meshes that were less stiff and more compliant with patients' tissues that Ethicon marketed for use in the pelvis. A midurethral sling device made from PVDF, (e.g., Dynamesh), or a mesh sling with less polypropylene and sealed edges, or a sling which contained a shorter piece of mesh and had arms consisting of suture like material would have also been a safer alternative.

Additionally, I continue to review internal Ethicon documents and the relevant body of medical literature on a continual basis. I also see women with chronic mesh complications on a continual basis. When I evaluate these women, whether it is in my practice or in a litigation setting, I see life-altering injuries that are related to the type of mesh these women were implanted with, the method in which the mesh was implanted,

where the mesh was implanted, but also the patient's lifestyle and makeup. In many of these cases, where one option may be less dangerous for a certain patient, in another patient that same option may be more dangerous. This is because of the unique patient specific concerns that pelvic floor surgeons, like myself, encounter on a daily basis when evaluating medical treatment for specific patients. Indeed, Ethicon and the inventor of the TVT recognized this very concept.

Unfortunately, although there have been a large number of studies and publications involving the TVT over the years, the quality of most of the studies is not good, and the amount of bias included in the studies and publications adds to the limited value that the studies offer about long term, severe and debilitating complications like chronic pain and erosions associated with the TVT. The most recent Cochrane review of mid-urethral slings, Ogah (2011), concluded that most trials involving mid-urethral slings had short follow-up and the quality of evidence was variable such that the quality of evidence for the majority of trials was moderate with a minority having low-to-moderate evidence.[266] Few trials reported outcomes after 1 year and long term adverse effects had yet to be determined. There are only a handful of RCTs involving the TVT that are long term, and major and long term complications would unlikely be picked up in these RCTs in part because they are designed with a primary endpoint of efficacy, not safety. The true incidence are more likely to be determined by registries or databases, but published registries do not track certain complications such as pain or dyspareunia, and have not been designed to monitor long term problems (Tamussino, 2001 and 2007; Kuuva 2002, Collinet, 2008, Dykorn 2010). This void in studying and presenting the true incidence and nature of long term and life altering complications, along with the biases inherent in many of the studies, and other factors, negates the value of the large majority of the

[266] Ohah, et. al., Minimally Invasive Synthetic Suburethral Sling Operations for Stress Unrinary Incontinence in Women: A Short Version Cochrane Review. Neurology and Urodynamics 30:284-291 (2011).

studies, and as a result, other sources of data such as published case series are relevant and important to truly understand the nature of these complications. Ethicon's internal documents and data, which are not publically available, present a very different picture of the TVT than the information that has been shared with patients and physicians.

I have done an in-depth review and analysis of the studies, and am prepared to discuss the studies including the small number of studies that have tracked chronic pain, dyspareunia and erosions on a long term basis. The Abbott study is particularly noteworthy, however. Abbott (2014) described a series of 347 patients evaluated for mesh related complications from 2006 -2010. Approximately 50% had a sling only and an additional 26% had a sling and TVM mesh. The median time from placement to evaluation was 5.8 months with a range of 0 – 65.2. This would mean that many of these patients would not have been captured in registries or RCT's with one year or less follow-up. Also only 26% were seen by another facility before attending one of the study sites, meaning that at least ¾ of these complications were not known to the implanting physician, again highlighting the limited utility of data at the primary site. The authors found 30% of patients had dyspareunia, 43% had erosion and 35% had pelvic pain.[267] This study highlights the degree and severity of the complications that mesh slings like the TVT are causing and, importantly, that physicians in the real world simply do not have the information about the severity of the problem. This is why it is extremely important for manufacturers of slings like Ethicon to accurately and fully report the risks and complications associated with the mesh devices to doctors – something Ethicon simply has not done.

L. It has been known since the launch of the TVT that the mesh can be difficult to remove, is susceptible to degradation, can rope, curl, deform, fray, and lose particles, and is a heavy weight mesh. However, Ethicon did not account for this facts in its dFMEA at the time of launch, and has failed to complete a proper risk analysis of these hazards

[267] Abbott, et. al., Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. American Journal of Obstetrics & Gynecology. (Feb. 2014).

Ethicon adopted revision 8 of the "Preventia" risk analysis prepared by Medscand AB for the TVT device as part of the TVT design history file.[268] This risk assessment was done on July 12, 2000, and omits numerous risks including that the mesh (1) can be difficult to remove, (2) is susceptible to degradation, (3) can rope, curl, deform (4) fray, and lose particles, and (5) is a heavy weight mesh. Ethicon does not have the previous versions of the risk assessments, revisions 1-7, which would include the version of the risk assessment performed prior to the launch of the TVT in late 1998, but it is reasonable to assume that if these risks had been identified in prior versions, they would still appear in revision 8 dated in July of 2000.[269] In April of 2002, Ethicon identified 11 risks that had been omitted from the Preventia revision 8 risk assessment. These risks include:

- Vaginal Extrusion
- Erosion/Urethral
- Perforation by Mesh
- Infection
- Vaginal Incision
- Urethral Tear
- Mesh Broken
- Torn Mesh
- Bent Needle
- Mesh Kinked(Twisted)
- Dull Needle

These are all risks that Ethicon knew or should have known at the time of launch of the TVT, and thus should have been assessed prior to launch. Because Ethicon failed to even identify these eleven risks, they also failed to assess the predicted and actual severity and frequency of these events, overall risk score, and actions needed to mitigate the risks of these failures. In addition, Ethicon also failed to identify and assess the other five risks discussed above at the time of launch 1998, or in 2002 when 11 new risks were identified, and still has

[268] ETH.MESH.01317508.
[269] Deposition of Dan Smith, 06-04-2013 794:8-18. Mr. Smith testified that "no person at Ethicon."

not conducted a proper risk analysis to this day.

Ethicon clearly did not consider and analyze that TVT mesh (1) can be difficult to remove, (2) is susceptible to degradation, (3) can rope, curl, deform (4) fray, and lose particles, and (5) is a heavy weight mesh as potential failure modes. These were critical analyses in designing and marketing the TVT product and needed to be performed to conduct an appropriate risk analysis and mitigation strategy. There is no mention of these failure modes in the dFMEA in Ethicon's possession at launch, and there has been no proper analysis of these failure modes to this day. It is opinion that Ethicon has failed to meet the standard of care of a reasonable device manufacturer by failing to include these known risks associated with the TVT device on its risk assessments at launch, and has failed to properly assess these known risks to this day.

V. CONCLUSION.

Ethicon has marketed and sold the TVT despite the fact that it is contains numerous characteristics that make it unsuitable for implantation in a woman's vagina. These characteristics include the following: (1) degradation of the mesh; (2) chronic foreign body reaction; (3) fraying, sharp edges and particle loss; (4) Infections and Bio-films; (5) roping and curling of the mesh; (6) loss of pore size with tension; (7) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (8) shrinkage/contraction of the encapsulated mesh.

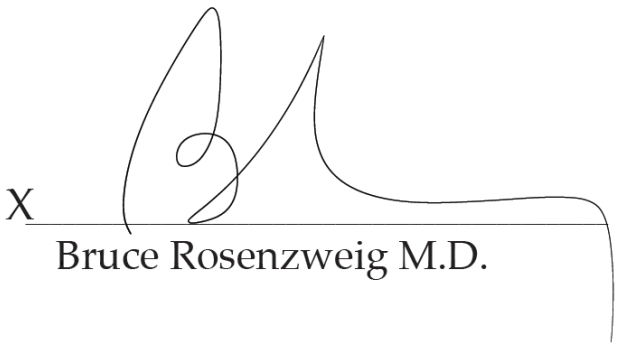
Not only does Ethicon sell a product which should never be put in the vagina, it failed to inform physicians and their patients about numerous risks associated with the product despite the fact that these risks were known before the product was launched. Ethicon has removed the ability of physicians to appropriately inform their patients of the risks and

benefits of the TVT and made it impossible for women to consent to the procedure. In addition, despite having knowledge to the contrary, Ethicon never informed physicians and their patients that the TVT could be toxic to their bodies. Finally, while keeping this information from women, Ethicon marketed its product with promotional pieces that did not disclose key conflict of interest information or the true complication rates of its products.

As a result of these failures as fully set forth in this report, the TVT has caused and will continue to cause a multitude of injuries in women, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, nerve injury, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

All opinions I have are to a reasonable degree of medical certainty. I understand discovery is still ongoing in this case and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions and expert reports of both Plaintiff and Defense experts. I have also reviewed the opinions of Dr. Uwe Klinge, Dr. Muhl, Dr. Vladimir Iakovlev, Dr. Elliott, and Dr. Anne Wilson, and incorporate those opinions herein. I also incorporate my past reports and testimony concerning the defects in the TVT and TVT-O.

Signed this 22nd day of May 2017.



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Bruce Rosenzweig M.D.

Exhibit B

AFFIDAVIT OF BRUCE ROSENZWEIG, M.D.

STATE OF ILLINOIS)
) ss
COUNTY OF COOK)

1. I, Bruce Rosenzweig, M.D., am over the age of 18 and fully competent to testify to the matters stated herein.

2. I have personal knowledge of the facts stated herein.

3. My knowledge of Randomized Controlled Trials ("RCTs") is informed not only by having reviewed large numbers of them, but also be personal participation in them.

4. I was involved in the development of a new medical device, an Amnio-infusion catheter. As part of that process, I helped to design an RCT to test placing the catheter into the uterus versus placing a single sham catheter. Once we started inventing the double lumen catheter, we considered different embodiments to determine which was most effective.

5. I worked with EMPI on developing and testing the Innova electrical simulator to treat SUI, and helped to design an RCT to test it. The RCT tested using a sham versus using an active simulator placed in the vagina. I was on the scientific advisory board of the company, so I was not an investigator, but I did help to design the RCT.

6. I was an investigator for an RCT involving the Lea Shield and Fem cap, which were both cervical cap contraceptives. They required a prescription, and the trial was designed to determine the appropriate size to achieve efficacy and to gain clearance from the FDA to sell the devices over the counter.

7. As I have discussed on many occasions, long-term clinical trials provide more reliable information about safety and efficacy than do short-term trials. However, the value of shorter-term trials is greater in evaluating efficacy than in evaluating safety.

8. For instance, the three-year Okulu study showing that using Ultrapro mesh to cure SUI is effective is valuable information because if the sling were ineffective, it would not cure SUI for that period of time. However, mesh complications often do not manifest for several years, so the length of a study is particularly important with regard to safety.

FURTHER, affiant sayeth naught.

In witness whereof, I have affixed my signature this 9th day of May, 2016.

Bruce Rosenzweig, M.D.

Subscribed and sworn to before me, this 9th day of May, 2016.

NOTARY PUBLIC

My Commission Expires:

8/25/17

OFFICIAL SEAL
KATIE ENGEL
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:08/25/17

Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** ***Shelby Anders v. Ethicon, Inc., et al.*** **Case No. 2:12-cv-05168**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CASE SPECIFIC RULE 26 EXPERT REPORT OF BRUCE ROSENZWEIG, M.D.

I am Bruce Rosenzweig, M.D. Any and all medical opinions rendered in this report represent my opinions, all held to a reasonable degree of medical certainty, and are based to a reasonable degree of medical probability and are based on scientifically reliable evidence.

I. BACKGROUND AND QUALIFICATIONS

I am currently an Assistant Professor of Obstetrics and Gynecology at Rush University Medical Center in Chicago, Illinois. I received my MD degree in 1984 from the University of Michigan in Ann Arbor, Michigan. Following graduation from medical school, I completed an Obstetrics and Gynecology Residency at Michael Reese Hospital in Chicago. In 1988, I attended a one year pelvic surgery fellowship at State University of New York in Syracuse, New York. Following that fellowship, I attended a two year Urogynecology and Urodynamics fellowship at UCLA Harbor General Hospital in Torrance, California. After graduating from the Urogynecology fellowship, I became a faculty member at the University of Illinois in Chicago. I started a Urogynecology program at the University of Illinois and also was the residency program director. In 1998, I went into private practice, and subsequently established a private

practice at Rush University Medical Center. I have also worked at John H. Stroger Hospital here in Chicago from May 2003 until November 2010 and Weiss Memorial Hospital as Associate Chair of Gynecology from February 2011 until July 2012. I have published numerous articles and given numerous lectures on the topics of pelvic organ prolapse, urinary incontinence and repair of pelvic organ prolapse. My full qualifications are set forth in my Curriculum Vitae attached to this Report as Exhibit A.

Throughout my career, I have performed over a thousand pelvic floor surgical procedures, including abdominal sacrocolpopexy, uterosacral suspensions, sacrospinous ligament fixations, native tissue repairs, biological graft repairs and synthetic mesh repairs. I have also used numerous synthetic pelvic mesh products, including both POP and SUI products. In addition, I have performed over 300 surgeries dealing with complications related to synthetic mesh, including the removal of numerous Ethicon devices. I was also invited by at least one mesh manufacturer to, and attended, both a POP mesh training seminar and SUI mesh training seminar overseas. In addition, I was also invited and attended training on another POP kit, the Bard Avaulta. I have expertise and knowledge regarding the pelvic floor and its reaction to materials and devices. I have also invented and designed products for gynecological uses. In addition, as discussed more fully below, I have reviewed numerous Instructions for Use and have approved and drafted Instructions for Use for products.

A list of all other cases in which, during the previous 4 years, I have testified as an expert at trial or by deposition, as well as my fee schedule, is attached as Exhibit B.

II. BASIS OF OPINIONS

In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Johnson & Johnson and Ethicon, Inc. (collectively referred to herein as “Ethicon”), depositions of Ethicon employees, and the records and depositions specific to

Mary Anders' case. All of the opinions I have are to a reasonable degree of medical and scientific certainty. I understand discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to corporate documents, depositions and the expert reports of both Plaintiff and Defense experts. The materials I have reviewed and relied upon to form my opinion for this report are attached as Exhibit C, as well as the documents cited throughout this report. I have also relied upon my TVT-S Expert Reports in the MDL [Waves] and Philadelphia (McGee). I have reviewed, relied upon and independently verified the MDL Prolift Expert Report of Dr. Daniel Elliot.

III. FINDINGS RELATED TO SHELBYANDERS

I reviewed the pertinent medical records and depositions pertaining to the care of Ms. Anders and below are my opinions of her care, surgery, and treatment, as well as her diagnosis and prognosis. Additionally, I conducted an independent medical examination on January 5, 2017, a record of which is below.

A. SUMMARY OF MEDICAL TREATMENT

Ms. Anders (DOB: 8/25/1950) at the time of her mesh implant was a 57 y.o. G2P2. Her medical history includes diabetes mellitus, type II, asthma, rheumatic fever, polycystic ovary syndrome, irritable bowel syndrome (IBS) with adhesions that caused chronic right upper quadrant pain, left adrenal tumor, palpitations, chest pain, multiple lipomas, external hemorrhoids, abdominal pain, gastric polyps, adrenal mass, hiatal hernia, esophagitis, stress urinary incontinence (SUI), pelvic organ prolapse (POP), fibroids, GERD, hypertension, hyperlipidemia, cystitis, urinary retention, hematuria, urinary tract infections (UTI), cystitis, leaking, frequency, urge incontinence, hesitancy, nocturia, pelvic pain, fecal incontinence, low

back pain radiating to the left leg, right shoulder pain, and knee pain. Her surgical history includes a tonsillectomy, right shoulder surgery, total abdominal hysterectomy (TAH), bilateral salpingo-oophorectomy (BSO), Marshall-Marchetti-Krantz (MMK), implantation of total Prolift and TVT-S, and a mesh revision procedure. She is a non-smoker.

On July 8, 1990, she complained of increasing menorrhagia, increasing prolapse symptoms, and mild leaking with heavy lifting. She had had uterine fibroids removed in 1974. On exam, it was noted that a moderate cystocele, small rectocele, and first to second degree uterine prolapse were present. The impression was descensus uteri, metrorrhagia, cystocele and rectocele.

On July 9, 1990, Ms. Anders underwent a TAH, BSO and MMK. The pre and post-operative diagnoses were pelvic pain, menorrhagia likely, endometriosis, fibroids, and SUI. The MMK was performed using 0-Chromic suture. She was discharged on July 13, 1990. It was noted that the reason for admission was pelvic pain, menorrhagia and SUI. Additional diagnoses included endometriosis, leiomyomata uteri and adenomyosis.

On August 9, 1999, she presented to the emergency room with complaints of abdominal pain. The diagnosis was IBS with adhesions.

On August 12, 1999, she was seen for severe right lower quadrant pain. It was noted that a CT of the abdomen suggested abnormalities of the distal small bowel and cecum.

On August 24, 1999, she was seen for IBS, right sided abdominal adhesions and GERD.

On November 3, 1999, she presented with complaints of diarrhea, right sided abdominal pain and reflux. The impression was IBS, erosive esophagitis and adhesions for a gallbladder scar.

On June 21, 2000, she presented with complaints of irritable bowel with right sided abdominal pain and reflux. The impression was IBS with right sided pain from adhesions and significant reflux with bile reflux and a history of erosions and stricture.

On July 25, 2001, she was noted to have a combination of GERD sufficient to have erosions and a mild stricture and IBS sufficient to make it difficult for her to go out without having the urgent need for a bathroom. She also had right upper quadrant pain, which was due to a combination of adhesions from her cholecystectomy and spasms in her colon. The impression was GERD with erosions and stricture and severe IBS.

On September 20, 2002, she was seen for right upper quadrant pain. It was noted that she had a history of irritable bowel syndrome, cholecystectomy, and erosive gastroesophageal reflux with esophageal stricture intra-abdominal adhesions, as well as a previous history of right upper quadrant abdominal pain, which was believed to be a combination of adhesions and colonic spasms.

On January 8, 2003, she presented with right upper quadrant pain, which was believed to be from fatty liver, adhesions and IBS. The impression also included GERD.

On April 10, 2003, she presented to the emergency room with complaints of hematuria, urinary frequency and bladder spasms. She was diagnosed with an acute complicated UTI and acute hematuria. Cipro and Pyridium were prescribed.

A urinalysis dated April 11, 2003 showed Ketones: trace, heme: large, Leukocytes: large, RBC: 13, hyaline casts: 21. A urinalysis dated July 9, 2003 showed WBC: 3-6, bacteria: 1+, epithelial cells: 3-6. Another urinalysis dated October 1, 2003 showed WBC: 1-2, bacteria: rare, epithelial cells: 3-4. It was noted that her problem was not a UTI.

On March 5, 2004, Ms. Anders was seen for chest pain.

On March 2, 2005, she presented for her annual gynecology exam. On exam, it was noted that a rectocele, cystocele and prolapse were present but were asymptomatic. She had quit HRT due to hypertension.

Negative urinalyses were reported on April 21, 2005 and March 1, 2006. A urinalysis dated October 19, 2006 showed Leukocytes: small, WBC: 3, RBC: 3, squamous epithelial: 15, bacteria: 1+. A urinalysis dated May 10, 2007 showed Squamous epithelial cells: rare, bacteria: few. Another urinalysis dated July 14, 2007 was negative.

On July 16, 2007, she presented to urogynecology for vaginal prolapse. She reported difficulty urinating and some hesitancy because she had to push her prolapse back into her vagina before she could void. She further reported no stress or urge incontinence. She reported some hesitancy when she voided due to the fact that she has to push her vaginal prolapse back in before she can void. She reported getting up at night approximately every hour to urinate. She was not sexually active due to the vaginal vault prolapse, and she denied any history of dyspareunia. She also had a history of cystitis, retention and hematuria, but a prior IVP was normal. On exam, a cystocele was noted, but it was hard to determine due to the vaginal vault prolapse, which was stage IV. A dime-size ulceration was noted on the right side of the prolapse. The impression was complete vaginal vault prolapse, ulceration on the vaginal vault prolapse, atrophic vaginitis, diabetes mellitus, and hypertension. A pessary was attempted, but she could not hold it. Traditional surgical procedures, as well as newer procedures including with mesh, were discussed. She was given information to read regarding these procedures, and the plan was to return to the clinic for a preoperative appointment. She was given Premarin vaginal cream to apply to the ulceration on her vault prolapse.

On August 1, 2007, she presented for biopsy of her vaginal vault prolapse ulceration. The pathology report showed squamous hyperplasia, perakeratosis and mild inflammation.

On August 8, 2007, Ms. Anders presented for a preoperative visit for anterior and posterior colporrhaphy with mesh, extraperitoneal colpopexy, pubovaginal sling, and cystoscopy. After an informed consent discussion, she consented to a total Prolift and TVT-Obturator (TVT-O). The assessment was total vaginal vault prolapse and urinary incontinence.

On August 14, 2007, Jeffrey Garris, MD performed an anterior and posterior colporrhaphy with mesh, extraperitoneal colpopexy, pubovaginal sling, and cystoscopy. The pre and postoperative diagnoses were urethral hypermobility, pelvic organ prolapse, stage IV, stress urinary incontinence, and vaginal ulceration. The operative report states, in pertinent part:

> Extreme care was taken during the placement of [the Prolift] needle and cannula to prevent pudendal neurovascular bundle injury, as well as rectal injury; indeed, no such injury could be appreciated. . . . There was no evidence of polyp, tumor, or suggestion of rectal injury and the Prolift cannula was noted to be excellently placed. The graft was then positioned with the respective superior and inferior arms in the anterior dissection. There appeared to be excellent position of the graft with minimal wrinkling.
>
> Extreme care was to position the graft tension-free. . . . the posterior arms were then placed, careful to make sure there was no wrinkling as well as to ensure that the graft was placed tension-free. After ensuring excellent positioning of the graft, the graft was then positioned tension-free. A second rectal exam was performed and noted with good positioning of the graft. Care was taken in position of the graft to prevent over-tensioning. The graft was once again noted to be tension-free.
>
> After placing the bilateral arms of the TVT Secure device, the cystoscope was then introduced after removing the Foley and the urethra was noted to be without polyps, defects, or graft. The cystoscope was then removed. The TVT was then positioned using the Credé maneuver, Initially, there was Leakage. The TVT Secure device was then repositioned until there was welling at the urethral meatus without leaks.

There were no complications.

On August 20, 2007, she presented to the emergency room with complaints of fever, nausea, vomiting, worsening in her energy level, and burning with urination. Urinalysis was positive for leukocytes and nitrites. The assessment was UTI complicated by resistance to Cipro clinically as well as prolonged catheterization, dehydration, constipation, and feart palpitations. She was admitted for IV antiemetics and fluid support and discharged the following day. On August 23, 2007, she was seen due to concern for yeast infection, and Diflucan was prescribed.

On August 28, 2007, Ms. Anders presented for a postoperative follow-up visit. She complained of anal incontinence, urgency with urination, and dysuria. On exam, there was no evidence of graft exposure or erosion. The following day, she called with complaints of right upper quadrant pain, flank pain, and dysuria. Later that day, she was admitted for observation secondary to a feeling of malaise and UTI. A pelvic CT was performed, and preliminary findings suggested pelvic hematoma with no evidence of ureteral obstruction, hyrdonephrosis, abscess, or other gross abnormality. On exam, there was excellent support of the vaginal walls and no evidence of graft exposure or erosion. With bimanual compression, there was minimal to no tenderness suprapubically. An abdominal and pelvic CT showed:

- Suspect large hematoma along the anterior margin of the vagina between the vagina and the urinary bladder, measuring 9.5 cm cephalocaudad by 5.0 cm transverse by 5.0 cm AP. Cannot exclude abscess
- Small fluid collections along the left lateral pelvic side wall
- Small left adrenal nodule
- Status post cholecystectomy with mild nonspecific dilatation of the common bile duct
- Minimal pelvocaliectasis but without evidence of significant hydroureter or ureterolithiasis. There may be some low grade obstruction to flow in both ureters secondary to inflammatory thickening of the bladder at its point of contiguity with the changes in the anterior vagina
- Right peripelvic cyst

There was some concern that her healing is slower than would typically be expected.

On August 30, 2007, Ms. Anders was still having pain, but had no urinary complaints. Macrodantin was prescribed.

On September 6, 2007, she called with concern for UTI and reported that her pain was coming back, rating it as an 8.

Ms. Anders presented to urogynecology for follow-up on October 1, 2007. She had some complaints of urinary urgency, frequency, as well as an occasion of urge associated urinary incontinence. She had no difficulty voiding and no defecatory dysfunction or anal incontinence. She had not yet resumed sexual activity. On exam, there was excellent support of the vaginal walls and no evidence of graft exposure or erosion. Urinalysis was within normal limits.

She presented for her final postop exam on October 17, 2007. She was doing well, but had some leaking when she got up in the morning. A urinalysis was negative. She was prescribed prophylactic Macrobid.

On October 19, 2007, she reported cystitis leaking, frequency and pain.

A urinalysis dated February 6, 2008 was normal.

On August 20, 2009, she reported back pain. She questioned whether the Prolift device could cause back pain and was told that it could not. The following day, she was seen for lower back pain radiating down her left leg for five days. She had been to the chiropractor with no relief.

On August 23, 2009 she presented with a yeast infection “raging all over her labia”.

On August 24, 2009 she present with lumbar back pain and an MRI showed DJD with a L5-S1 disc protrusion.

On September 14, 2009, she underwent a lumbar epidural steroid injection. It was noted that an MRI of the lumbar spine showed evidence of a degenerative disc with disc bulging at the

L5-S1 level. She complained of coccyx and low back pain with radiation to the left. On November 11, 2009, a urinalysis showed: Ketones: 2+, protein: Large, nitrite: Positive, blood: large, leukocytes: Positive. A CT of the abdomen and pelvis was performed due to hemorrhagic cystitis. The impression was

- Status post cholecystectomy with stable mild nonspecific dilatation of the common bile duct. No appreciable intrahepatic duct dilatation
- Stable left adrenal nodule. Measuring 12 mm in size
- Right peripelvic renal cyst and tiny lower pole left renal cyst are documented. These were shown to be simple cysts on 08/29/2007
- No evidence of nephrolithiasis, pelvocaliectasis or ureterolithiasis
- multiple diverticula arise from the colon consistent with diverticulosis but without evidence of diverticulitis
- Postoperative changes in the pelvis consistent with prior hysterectomy and Prolift procedure
- Negative for stones

A urinalysis dated November 13, 2009, showed: Leukocytes: Small, WBC: 36, RBC: 6, squamous epithelial cells: 15, bacteria: 2+, hyaline cast: 16.

On December 2, 2009, she was seen for swelling in her ankles. She reported that she had an implant put in 4 years prior to help support the pelvic floor, and she had heard that they have caused erosion of the bladder and was concerned about it causing the UTI symptoms. She reported pelvic pain at times. She was on Cipro, and urinalysis results were: Leukocyte esterase: Moderate. Her urine from 11/13/2009 was reviewed, and it showed bacteria and it was after treatment. Her CT was reviewed and it showed stranding in the pelvic region around the Prolift device. It was noted that she had recurrent UTIs since the mesh implant procedure. She was prescribed Flagyl, Doxycycline and Cipro. She was referred to urologist T. Fleming Mattox, MD for chronic UTI. Urine culture results dated December 4, 2009 were: Mixed bacterial flora. 25,000-50,000 colony forming units per ml.

On December 10, 2009, she presented to Dr. Mattox with complaints of recurrent UTIs for two years, with two occurring the prior year. Of these, all were culture confirmed. Nothing was noted to improve her infection rate. Nothing was noted to exacerbate her bladder infection rate. She stated she had symptoms all the time. It was noted that she had Prolift placed in 2007 and she developed a bladder infection. She continued to have bladder infections and was concerned that her mesh was infected. She recently had a bladder infection and passed clots. She was postmenopausal and denied symptoms of frequency, urgency and loss of urine with stress. She denied any symptoms of genital prolapse. She denied nocturia or wearing protective undergarments. Specific bowel habits were not noted. Fecal incontinence was denied. Use of laxatives, suppositories or enemas to facilitate bowel movements were denied. Her incontinence quality of life scale was: 44 (Range 24 - 98). Her activity quality of life scale was: 75 (Range 36 - 149). Higher numbers indicate decreasing quality of life. A review of systems included dysuria and hematuria. A urinalysis was negative. A post-void residual was 0 ml. On exam, estrogenation of the pelvis appeared to be adequate. Levator musculature was noted to be good. A grade 2 cystocele was appreciated. No mesh erosion was appreciated. A pelvic organ prolapse standing system was: Aa.: 0.0, Ba: 0.0, C: -5.5, genital hiatus: 5.0, perineal body: 4.0, vaginal length: 8.0, Ap: -2.0, Bp: -2.0, D: N/A. The impression was lateral cystocele, hematuria, incompetent or weakening of pubocervical tissue, Pelvic Organ Prolapse Quantification (POPQ) Stage II, and recurrent urinary tract infections. It was noted that she was having episodes of gross hematuria and recurrent UTIs, and with her history of mesh, Dr. Mattox was concerned about mesh erosion. The plan was a cystoscopy, which was performed on January 7, 2010. There were no lesions and no signs of any foreign body in the bladder. A urinalysis was negative.

She present for follow-up on April 8, 2010. It was noted that she had recently been treated for a UTI with Cipro and then her medicine was changed to Ceftin after a culture revealed E. coli resistant to Cipro. She complained of a persistent UTI. A urine dip was positive. The impression was lateral cystocele, hematuria, incompetent or weakening of pubocervical tissue, Pelvic Organ Prolapse Quantification (POPQ) Stage II, and recurrent urinary tract infections. Urine culture results dated April 10, 2010 showed E. coli, identified by an automated biochemical system, 25,000-50,000 colony forming units per ml, resistant to Cipro. Urelle and Macrobid were prescribed.

Ms. Anders presented for follow-up on May 24, 2010. She was having recurrent UTIs and was taking probiotics daily. Cipro and Macrobid were prescribed. Urine culture results showed E. coli, 50,000-100,000 colony forming units per ml. On May 27, 2010, she reported that she was not feeling much better.

She presented for follow-up on July 15, 2010. She was symptom free with the Macrobid suppression. The plan was Estrace cream, Macrobid and probiotics. She returned on September 23, 2010 and reported that she was better on this regimen. She was instructed to return in 6 months, which she did on March 24, 2010. The regimen remained the same.

A urinalysis dated August 17, 2011 showed: WBC: 1+, mucus threads: present, bacteria: Few.

Ms. Anders returned for follow-up on September 29, 2011 with complaints that she did not feel well and she thought that she may have a UTI. Her urine only showed blood, and this was not something new for her. She did not have general body aches, just pain in her lower abdomen. A urinalysis showed moderate blood. Urine culture results showed less than 10,000

colony forming units of bacteria per milliliter of urine. Macrodantin and Estrace prescriptions were refilled.

On Feburary 13, 2012, she presented with pelvic pain since the mesh implant procedure. Urinalysis results were: Ketones: 3+, protein: 1+, blood: 1+. The assessment was pelvic floor device contributing to pelvic pain, and she was referred to Dr. Mattox.

She saw Dr. Mattox on February 16, 2012. She had been seeing blood in her urine and described her urine being dark at times. She noted some urethral irritation as well. She had some blood in her urine that day. She had been on Metformin and had noticed that her urine output was down. It was noted that she was being evaluated for Lupus. Her Pain and Urinary Frequency (PUF) score was 7. She was being evaluated for lupus. She had stopped the Metformin. A urinalysis showed trace blood and 70+ leukocytes. The plan was Estace, Macrobid and probiotics.

A urinalysis dated March 13, 2012 showed squamous epithelial cells: 10, hyaline cast: 6, bacteria: 1+, mucus: few.

On April 11, 2012, she presented with complaints of severe abdominal pain and pain worse through the back. The abdomen was tender to touch and swollen. The assessment was abdominal pain, severe, with pelvic floor device. A CT of the abdomen and pelvis was performed. The impression was:

- I do not appreciate any obvious interval change as compared to 11/11/2009 which would help explain symptoms of abdominal pain.
- Note is again made of a large hiatal hernia. there is a generous common bile duct but this is seen in the setting of cholecystectomy and so is of more questionable clinical significance
- Renal cysts are again noted. Mild colonic diverticulosis is again noted

Urine culture results dated April 12, 2012 showed mixed urogenital flora, less than 10,000 colonies/ml.

An EGD was performed on April 12, 2012 due to odynophagia, abdominal pain and pneumonia, and it was negative except for gastric fundic gland polyps and hiatal hernia with a foreshortened esophagus.

She was seen on April 30, 2012 for abdominal pain, gastric polyps, adrenal mass, hiatal hernia, and GERD.

On October 24, 2012, she was seen for dysuria. The diagnosis was UTI and Macrobid was prescribed.

On March 13, 2013, she presented with complaints of pelvic pain. She had done relatively well since the mesh implant surgery, but for the prior year, she had developed some lower abdominal pain that had not been explained. She stated that the pain had been intermittent, but it had become more frequent. It was very distressing to her. She was having some issues with fecal incontinence as well, that had started over the last year. She felt like she had bowel movement urgency and problems making it to the bathroom with solid stools. This was happening 1 to 2 times per day. She qualified the pain as a sharp, shooting pain. She could not pinpoint anything that alleviated it. She had also noticed some tingling in her large toes on both feet. She reported that she had a colonoscopy in the prior couple of years, which was within normal limits. She complained of some urinary frequency, as well as incontinence at night. Most of the time, she could not tell what makes her leak urine, but she was going through approximately 2 mm pads per day. She was not currently sexually active, due to fear that intercourse would disrupt the surgery that she had. She had no recurrence of prolapse symptoms and was overall very happy that she had her surgery done. On exam, there was some tenderness

in the left and right lower quadrants, as well as the suprapubic area. The vaginal mucosa revealed severe vaginal atrophy. A cough-stress test was negative. A POP-Q exam results were anterior a and b at 0, point C was -5, total vaginal length was 6, and posterior a and b are at -2.5. A urinalysis done was positive for 15 mg per 61 of ketones and trace protein. It was negative for blood, leukocytes and nitrites. The impression was vaginal atrophy, pelvic pain, cystocele and fecal incontinence. In regards to her vaginal atrophy, Dr. Mattox recommended treating this, as it could be part of the contributory factor to her pain, as well as her urinary frequency. He prescribed Premarin vaginal estrogen cream. He informed her that he could not blame all of her lower abdominal pain on the vaginal atrophy and that she still may need further evaluation. He referred her to pelvic floor physical therapy because of her issues with pelvic pain, as well as frequency and fecal incontinence. He discussed with her that there was a possibility that there was scar tissue surrounding the transvaginal mesh that was contributing to her symptoms. In regards to her recurrent cystocele, this was not bothersome to her and she was satisfied with the results that she had gotten from the surgery. Dr. Mattox discussed with her the possibility of having trigger-point injections done, but she declined this because of her diabetes

Ms. Anders underwent pelvic floor physical therapy from April 15, 2013 to June 3, 2013.

On June 5, 2013, she presented for follow-up for pelvic pain. She had discomfort in her right lower quadrant for the prior 3 years. It was noted that a computerized tomography scan done in April 2012 did not show any reason for her pain. She stated that she believe that the estrogen cream had helped her with her symptoms. She did not feel like the pelvic floor physical therapy did much to relieve her pain. She actually felt like it caused her more soreness. She felt like her right-sided pain was about the same as it was three months prior. She was tearful with frustration of having this discomfort for so long. Treatment options were discussed, including

surgical procedures where scar tissue and partial mesh excision could be done to see if releasing the mesh arms would improve her discomfort.

On August 7, 2013, she presented with complaints of urge incontinence. It was noted that she had pelvic pain for several years, but it seemed to be better and stabilized. In the prior three months, she had only had a couple of episodes of pain, but she described these episodes as severe pain. She believed they alternated between left and right. Her pain was not her main complaint. It was the fact that she had urge incontinence at night that had been getting worse. She had nocturia three to four times per night, and when she woke up in the middle of the night to urinate, she would not make it to the bathroom before she soaks herself. She felt like this was getting worse. She also complained of some voiding dysfunction during the day. She had urinary hesitancy and felt like her stream was slower than it should be. She believed that her diabetes was worse and felt that this may be a contributing factor to her urinary symptoms. It was noted that there was some recurrent prolapse in the anterior vaginal wall, but she did not feel like it bothered her enough for her to undergo surgery or a pessary trial at that time. The impression was pelvic pain, urinary urgency and voiding dysfunction, as well as vaginal atrophy. Premarin cream was prescribed.

On February 4, 2014, Ms. Anders was diagnosed with a UTI.

On February 18, 2014, she presented with continued episodes of pelvic pain, which was better than it was prior to the physical therapy. She pinpointed very specific activities, like lifting her grandson, that caused her to have right-sided pelvic pain for 1 to 2 days, which would spontaneously resolve on its own. She was bothered by this, but did not want any intervention at that time. She reported fecal incontinence that was not liquid stool, but urgency. The impression

was atrophic vaginitis, recurrent prolapse, and fecal incontinence. Premarin cream was prescribed.

On February 24, 2015, she presented for follow-up for pelvic pain and fecal incontinence. It was noted that she had problems with the Prolift since 2013 and had minimal improvement in her symptoms. She reported that she quit her job due to the fecal incontinence. She again pinpointed her vaginal pain to be directly related to picking up her grandchildren. She would have severe pelvic pain the following days. This last episode that she had was approximately 6 weeks prior and was the worst that she had had. The pain lasted for several days and she was quite miserable from the discomfort. As far as her fecal incontinence is concerned, she was having urgency and leakage of solid stools. She could not pinpoint anything that tended to cause her fecal incontinence, such as a particular food. This was happening 1 to 2 times per month. The possibility of having a transvaginal mesh release was discussed, but she had a lot going on with her family and wanted to put this off until later. For the fecal incontinence, InterStim was discussed. Regarding the vaginal atrophy, she felt that she had had some improvement with estrogen cream and wanted to stay on it. The impression was vaginal pain, pelvic pain and fecal incontinence.

On August 18, 2015, she was seen for follow-up for vaginitis and chronic pelvic pain that started after placement of the transvaginal mesh. She stated that she wanted to move forward with a surgical release of the mesh to see if she could get some relief. She continued to have pain, mostly on her right and with activity. She also reported fecal incontinence. Premarin cream was continued.

Ms. Anders presented for follow-up on February 16, 2016 for chronic pelvic pain, urinary urgency, and fecal incontinence. She reported that her conditions were the same since the past

visit, but she believed that the estrogen cream helped with her pain and was not interested in surgery for mesh release/removal.

On April 26, June 16, and July 19, 2016, she was seen for chest pain, and on June 13, 2016, she was seen for syncope and dizziness. She reported no urinary urgency, no dysuria and no change in the nature of her urine. She reported no change in menses, no dysmenorrheal, no vaginal discharge, and no pelvic pain.

She presented on September 1, 2016 for follow-up for chronic pelvic pain that started after the mesh implant procedure. She reported that estrogen cream seemed to help, but she continued to have discomfort in her right pelvic area that was worse with activity. She wanted to see if she was a candidate for surgery. She was referred to urogynecologist Thomas Wheeler, MD.

On October 24, 2016, she reported an episode of rectal bleeding, lower abdominal pain, and several episodes of bright red rectal blood mixed with mucus. This resolved on its own. She did have external hemorrhoids. It was noted that she had chronic pelvic pain following the mesh implant procedure.

Ms. Anders presented to Dr. Wheeler on November 3, 2016 for an opinion regarding ongoing chronic pelvic pain and right lower quadrant pain since placement of the mesh. It was noted that she had tried pelvic floor PT and estrogen cream without improvement. She described her pain as a constant dull ache in the deep right lower quadrant. She also described a tearing sensation followed by extreme soreness when exacerbated by any activity that required her to "use my abdominal muscles," such as lifting her grandchildren, with the effect lasting for 2-3 days. She also reported one episode of intense suprapubic abdominal pain approximately 2 weeks prior followed by an episode of bright red rectal bleeding. She complained of urinary

urgency, frequency, enuresis, and fecal incontinence that did not improve with pelvic floor PT. She was not sexually active. On exam, the vagina was moist and moderately rugated with no visible mesh. Bridging of the Prolift mesh was appreciated right anterior/apical with reproduction of her right lower quadrant abdominal pain – non-distractable. Tenderness was reproducible on the right anterior cephalad arm of the anterior mesh. The assessment was chronic pelvic pain related to mesh on tension. Ms. Anders was counseled that due to the reproducibility (and inability to distract her from) her pain with palpation of the mesh on tension, she is most likely having referred pain to her right lower quadrant as a result of the mesh. She was counseled on her option to proceed to the OR for revision of the mesh with an approximately 3-4 cm incision to release the tension of the mesh in that one area. After an informed consent discussion, the plan was to proceed with mesh revision and cystourethroscopy.

Ms. Anders was seen for a preoperative visit on November 17, 2016. A urinalysis was negative. The planned surgery was revision of right proximal Prolift arm and cystoscopy.

On November 22, 2016, Dr. Wheeler performed a mesh revision with release of right proximal anterior arm. The pre and postoperative diagnosis was vaginal pain at proximal right anterior Prolift arm with banding. Cystoscopy revealed no mesh in the bladder and bilateral efflux of dye. There were no complications.

On November 28, 2016, Ms. Anders reported via phone that she had some bleeding the day prior after doing some housework, but it had subsided. She also reported some bladder spasms and burning off and on with urination.

B. EXAMINATION

I conducted an examination of Ms. Anders on January 11, 2017. My record of that examination follows:

Ms. Anders is a 66 year old gravida 2 para 2. Her last period was at age 36 and was surgically induced. Her last pap was greater than 10 years ago. Her last mammogram was in 2016. She had a follow-up diagnostic mammogram but this did not show any significant pathology. She is allergic to Aspirin, Ibuprofen, Penicillin, Sulfa antibiotics, Flexeril and Ace inhibitors. Her medications include Spironolactone, Metoprolol, Omeprazole and Norvasc. Her medical problems include hypertension, diabetes and GERD. She has a history of lumbar radiculopathy which has since resolved and she has a history polycystic ovarian syndrome. Her surgical history is remarkable for gall bladder removal, hysterectomy, tonsils and adenoids removal, rotator cuff surgery, the Prolift surgery with a mid-urethral sling and a mesh revision surgery in 2016.

She has had 2 vaginal deliveries the largest being 9 lbs 9 ozs. Her menses began at age 13 and ceased at age 36 and was surgically. She denies a history of STD's. All of her paps have been normal. Her family history is remarkable for hypertension in her father, cardiovascular disease in her mother, prostate cancer in her father and breast cancer in her sister. She denies smoking or alcohol use.

Prior to her sling she was having severe pelvic organ prolapse. Her prolapse was completely through the vagina. She was uncomfortable from the prolapse and it was causing some pressure. The prolapse made it so that she could not urinate. She would need to lie down to reduce the prolapse in order to urinate. She had an occasional constipation. She does not recall leaking urine. She had no pelvic pain. She had an occasional urinary tract infection. She was not sexually active. She did note that she would develop ulcers on the prolapse.

After the mesh surgery she had a severe infection and was quite ill immediately after the procedure. She developed bladder and kidney infections where she would see blood and pus in her urine but she felt she could completely empty her bladder.

After the post operative period she kept getting urinary tract infections and was placed on prophylactic antibiotics and Premarin vaginal cream. She also began to leak urine and was having urinary frequency and urgency. She began to develop bladder spasms and pain in her pelvis particularly on the right side. It was so uncomfortable she thought she had appendicitis but she had no fever or other symptoms of appendicitis. She also occasionally lost control of her bowels. She was not sexually active during this time.

After her revision procedure she states that her pelvic pain is different but still present. It is a stabbing pain and does not last as long as prior to the revision surgery. Her bladder spasms have recurred recently as have the symptoms of a urinary tract infection. She still has some stress incontinence and frequency and urgency especially upon standing. She has some leakage with urge. She feels like she empties her bladder completely but does have dysuria, described as a burning sensation upon emptying.

On her exam she is 5’ 6” tall and 198 lbs. Her blood pressure is 159 /93. Her pulse is 73. Her HEENT exam is normal. . Her sensorium is normal. Her body habitus is normal aside from her weight. Her back is non-tender to palpation. There is no CVA tenderness. Her abdomen she has an old cholecystectomy scar and a low Pfannenstiel scar; however, her abdomen is soft non-tender with no guarding or rebound. Her lower extremities are non-tender without edema. Her abductor and adductor muscles are of a normal strength and are non-tender. She does have a mild degree vulvo-vaginal atrophy. She has a stage I cystocele. Her supine stress test is negative. Her levators are mildly tender 2- 10 bilaterally. Her obturator internus muscles are non-tender. The

mid-urethral sling is palpable, but is non-tender. The apical arms of the Prolift are palpable as is the apical portion of the Prolift it is non-tender to palpation. The bi-manually exam shows the uterus and cervix are surgically absent. The adnexa are non-palpable.

C. OPINIONS

Based on my background, education, training, and experience, as well as the medical records and deposition testimony offered in this case, it is my opinion that Dr. Garris' care and treatment of Ms. Anders met the standard of care. The pre-operative evaluation of the patient met the standard of care. The mesh implant procedure was indicated due to Ms. Anders' pelvic organ prolapse and stress urinary incontinence and was performed within the standard of care with no evidence of surgeon error or deviation from the procedural steps. There was no evidence of any surgical complications, excess blood loss, excess surgical duration, or surgical site contamination in the records.

Similarly, it is my opinion that Dr. Wheeler's mesh revision procedure met the standard of care. The pre-operative evaluation of the patient met the standard of care. The mesh excision procedure was indicated due to vaginal pain at proximal right anterior Prolift arm with banding and was performed within the standard of care with no evidence of surgeon error or deviation from the procedural steps. There was no evidence of any surgical complications, excess blood loss, excess surgical duration, or surgical site contamination in the records.

Based upon my medical education, experience, my review of the currently available medical literature, Ms. Anders' medical records and my examination of her, I have formed opinions regarding Ms. Anders' current complications. In coming to those conclusions, a broad differential diagnosis was reviewed and considered her medical and surgical history, which includes: diabetes mellitus, type II, asthma, rheumatic fever, polycystic ovary syndrome, IBS

with adhesions that caused chronic right upper quadrant pain, left adrenal tumor, palpitations, chest pain, multiple lipomas, external hemorrhoids, abdominal pain, gastric polyps, adrenal mass, hiatal hernia, esophagitis, SUI, POP, fibroids, GERD, hypertension, hyperlipidemia, cystitis, urinary retention, hematuria, chronic UTIs, cystitis, leaking, frequency, urge incontinence, hesitancy, nocturia, pelvic pain, fecal incontinence, low back pain radiating to the left leg, right shoulder pain, knee pain, a tonsillectomy, right shoulder surgery, TAH, BSO, MMK, implantation of total Prolift and TVT-S, and a mesh revision procedure.

None of these factors increased the risk for developing her symptoms. The back, leg, shoulder, flank, and knee pain are in locations on Ms. Anders' body other than the pelvic floor. While she did complain of pelvic pain and lower quadrant pain in the 1990s, there is no indication that she had chronic pelvic or vaginal pain prior to the mesh implant procedure. In fact her hysterectomy would have solved any issues from fibroids, adenomyosis or endometriosis. The MMK procedure was performed with absorbable sutures. She did have polycystic ovary syndrome, but her ovaries have been removed. While she had undergone other pelvic surgeries, there was no excessive scarring noted at the time of the mesh implant procedure. While she complained of hesitancy prior to implant procedure, this was noted to be due to her prolapse. As stated, she did have a pre-implant history of cystitis, urinary retention and hematuria, but an IVP was normal. While she complained pre-implant of urinary urgency and frequency, these complaints were more severe and more frequent after the procedure. It appears that she had a UTI prior to the mesh implant procedure, but there is no indication that she had chronic, recurrent UTIs as she is suffering from currently. Her vaginal atrophy has improved with estrogen cream.

I have come to the following conclusions regarding Ms. Anders' conditions to a reasonable degree of medical certainty:

1. As a result of the implantation of the transvaginal mesh products, including the mesh characteristics discussed below, and the subsequent reactions and surgical revisions, Ms. Anders has sustained the following injuries, which are most likely permanent in nature: mesh contraction placing the mesh under tension and deformation with bridging and scarring due to CFBR and chronic inflammation, cystitis, urinary retention, hematuria, dysuria, leaking, frequency, urge incontinence, urgency, hesitancy, chronic UTIs, yeast infection ranging over the labia, chronic pelvic pain, vaginal pain, mesh bridging, urethral irritation, pelvic hematoma, fecal incontinence, and the need for a mesh revision procedure.

2. It is my opinion, to a reasonable degree of medical and scientific certainty, that the debilitating injuries suffered by Ms. Anders, which are listed above, were directly caused by the transvaginal mesh devices, including the following polypropylene mesh characteristics: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh that was never meant to be implanted inside the human body and is incompatible with the naturally occurring condition of the vagina including peroxides and bacteria; (d) deformation, rigidity, fraying, roping, cording and curling of the mesh; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; and (h) the difficulty and/or impossibility of removing the devices.

3. To a reasonable degree of medical certainty, contraction, shrinkage, deformation, degradation, and rigidity of the TVT-S and total Prolift, the materials used to manufacture the

TVT-S and total Prolift, and the design of the TVT-S and total Prolift, or a combination of these factors, caused Ms. Anders' injuries, as listed above.

Based upon my medical education, experience, my review of the currently available medical literature, Ms. Anders' medical records and my examination of her, I have come to the following conclusions regarding Ms. Anders' prognosis and chance for recovery to a reasonable degree of medical certainty:

1. Chronic Pelvic Pain: Prognosis is poor. It is highly unlikely, even with aggressive physical therapy, biofeedback, medication use and/or surgical intervention, for Ms. Anders to have complete resolution of her chronic pelvic pain.

2. Urinary Dysfunction (cystitis, urinary retention, hematuria, dysuria, leaking, frequency, urge incontinence, urgency, hesitancy): Prognosis is poor. It is highly unlikely, even with aggressive physical therapy, biofeedback, medication use and/or surgical intervention, for Ms. Anders to have complete resolution of the urinary dysfunction.

3. Chronic Urinary Tract Infections: Prognosis is poor. It is highly unlikely, even with aggressive physical therapy, biofeedback, medication use and/or surgical intervention, for Ms. Anders to have complete resolution of the chronic urinary tract infections.

4. Fecal Incontinence: Prognosis is poor. It is highly unlikely, even with aggressive physical therapy, biofeedback medication use and/or surgical intervention, for Ms. Anders to have complete resolution of her fecal incontinence.

Based upon my review of Ms. Anders' medical records, my experience and education, and review of the available medical literature, I currently hold the following opinions to a reasonable degree of medical certainty:

1. Ms. Anders was not able to make a fully informed medical decision regarding the implantation of the TVT-S and Prolift mesh because Ethicon failed to fully disclose the risks and complications (both early and late) in the TVT-S and Prolift Instructions for Use. As discussed above, and elsewhere in this report, Ms. Anders did not receive information about the above risks because Ethicon did not disclose them fully in its IFUs, and surgeons, including the implanting surgeon in Ms. Anders' case, were not made aware of them. This is true despite information readily available to Ethicon about these risks, which predate the launch of the device. Because of this, Ms. Anders' implanting surgeon could not pass this information on to her and properly consent her about the risks associated with the TVT-S and Prolift devices. Ms. Anders was unable to make a fully informed decision about having the devices implanted. As a result, to a reasonable degree of medical certainty, Ms. Anders suffered injuries that were not disclosed by Ethicon, and the inadequate disclosure of these risks was a substantial factor and/or cause of Ms. Anders' injuries.

2. Ms. Anders' implanting surgeon was not able to provide the necessary and required information to Ms. Anders for an informed consent because Ethicon failed to fully reveal such information and failed to fully evaluate said information prior to launch.

3. Ms. Anders has developed complications, as described above, as a result of the TVT-S and Prolift being implanted in her body, causing chronic inflammation, foreign body reaction, scarring, contraction, shrinkage, deformation and degradation of the mesh due to the defects of the mesh described above and throughout this report.

4. As a result of these complications from the TVT-S and Prolift devices, Ms. Anders has suffered damages and will continue to suffer future damages.

5. These complications have caused a significant impact on Ms. Anders' quality of life. Currently, Ms. Anders has been forced to reduce and/or alter her activities due to her injuries, as set forth above.

Safer alternative designs, rather than the TVT-S and Prolift polypropylene mesh products, existed for this patient. I have experience with many of these safer alternative designs, and based on my experience and review of medical literature and other materials, it is my opinion that these alternative designs were safer and feasible for Ms. Anders. These safer alternative designs include:

(1) the use of sutures, including delayed absorbable sutures like PDS, in a colposuspension procedure, like the Burch; a uterosacral ligament suspension and a sacrospinous fixation; an anterior and posterior colporrhaphy; a sacrocolpopexy and a sacrohysteropexy;

(2) autologous fascia lata and an autologous fascia sling;

(3) an allograft sling such as Repliform; and

(4) a sling with less polypropylene such as Ultrapro.

These safer alternative designs would have significantly reduced the risk of the injuries to Ms. Anders, as I have described in my report, that were a result of the specific design flaws of the TVT-S and total Prolift, including banding, scarring, cording, scar plate, chronic inflammation, chronic foreign body reaction, dense, heavy, and frayed, rough edges. If any of these safer alternative designs been used for Ms. Anders, she would not have suffered the injuries I set forth in my report, as her injuries were caused by the specific design flaws of the TVT-S and total Prolift discussed above.

Finally, I have reviewed Ms. Anders' medical bills as set forth in my reliance list. I feel that they were reasonable and necessary charges to treat the complications and injuries that, to a reasonable degree of medical certainty, were caused by the TVT-S and Prolift devices, as discussed above.

VI. CONCLUSION

All opinions I have are to a reasonable degree of medical certainty. I understand discovery is still ongoing in this case and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, the depositions of the implanting and explanting surgeons, corporate documents, depositions and expert reports of both Plaintiff and Defense experts.

Signed this 15th day of January, 2017.

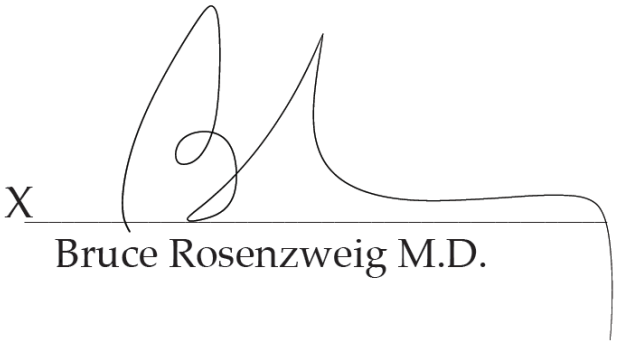

Exhibit A

CURRICULUM VITAE

NAME: **Bruce A. Rosenzweig, M.D.**

ADDRESS: 175 East Delaware Suite 8909
Chicago, Illinois 60611

DATE OF BIRTH: November 16, 1957

PLACE OF BIRTH: New York City, New York

MARITAL STATUS: Married

EDUCATION:

Fellowship

1989 - 1991 Urologic Gynecology and Urodynamics
Harbor/UCLA Medical Center
Department of Obstetrics and Gynecology
Torrance, California

1988 - 1989 Pelvic Surgery
State University of New York
Department of Obstetrics and Gynecology
Syracuse, New York

Residency

1984 - 1988 Obstetrics and Gynecology
Michael Reese Hospital and Medical Center
Department of Obstetrics and Gynecology
Chicago, Illinois

1987 - 1988 Administrative Chief Resident

Graduate

1980 - 1984 University of Michigan Medical School
Ann Arbor, Michigan

1980 - 1984 Academic Tuition Scholarship
University of Michigan Medical School

Undergraduate

1976 - 1980 University of Michigan
Ann Arbor, Michigan - BS in Zoology

1976 University of Michigan Alumni Scholarship,
Illinois Chapter

1976 Bronsted Freshman Prize

POSITIONS/APPOINTMENTS:

2011- 2012	Associate Chair Weiss Memoral Hospital Department of Gynecology Chicago, Illinois
2003- 2010	Attending Physician John H. Stroger Jr. Hospital Department of Obstetrics and Gynecology Chicago, Illinois
2002 - Present	Attending Physician Department of Obstetrics and Gynecology Rush Presbyterian St. Luke Hospital Chicago, Illinois
2002 - Present	Assistant Professor Rush Medical College Chicago, Illinois
1997 - 2005	Attending Physician Department Obstetrics and Gynecology Mercy Hospital and Medical Center Head Urogynecology Chicago, Illinois
1995 - 1998	Attending Physician Department of Women's Health Department of Veterans Affairs Westside Veterans Hospital Chicago, Illinois
1994 - 1998	Associate Professor Department of Obstetrics and Gynecology and Department of Urology University of Illinois, College of Medicine Chicago, Illinois
1992 - 1994	Assistant Professor Department of Urology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Associate Residency Program Director Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Head of Gynecologic Urology Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Attending Physician Department of Obstetrics and Gynecology Michael Reese Hospital and Medical Center Chicago, Illinois

POSITIONS/APPOINTMENTS (Cont):

1991 - 1994	Assistant Professor Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1990 - 1991	Clinical Instructor Department of Obstetrics and Gynecology UCLA School of Medicine Los Angeles, California
1989 - 1991	Attending Physician Department of Obstetrics and Gynecology Harbor/UCLA Medical Center Torrance, California
1988 - 1989	Clinical Instructor Department of Obstetrics and Gynecology State University of New York Health Science Center Syracuse, New York
1988 - 1989	Attending Physician Department of Obstetrics and Gynecology Crouse-Irving Memorial Hospital Syracuse, New York

PROFESSIONAL SPORTS TEAM PHYSICIAN

2011- Present	Chicago Sky Women's Basketball Team

LICENSURE:

1984	State of Illinois, #036-071719
1988	State of New York, #175147 (inactive)
1989	State of California, #G065470 (inactive)
1985	State of Illinois Controlled Substance, #003-136655
1985	DEA #BR0291815

SPECIALTY BOARDS:

1985	Diplomate of National Board of Medical Examiner
1991	Diplomate of American Board of Obstetrics and Gynecology (Recertofoed 2005)

JOURNAL EDITORIAL BOARD:

JOURNAL OF GYNECOLOGIC SURGERY
JOURNAL REVIEWER AND CONSULTANT

OBSTETRICS AND GYNECOLOGY

JOURNAL OF GYNECOLOGIC SURGERY

SURGERY GYNECOLOGY AND OBSTETRICS
ABSTRACTOR: International Abstracts of Surgery;

INTERNATIONAL UROGYNECOLOGY JOURNAL

JOURNAL EDITORIAL BOARD (Cont):

JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION
CONSULTANT: Diagnostic and Therapeutic Technology
Assessment (DATTA),

AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY

PSYCHOSOMATIC MEDICINE

SOUTHERN MEDICAL JOURNAL

JOURNAL OF HOSPITAL MEDICINE

INTERNATIONAL JOURNAL OF OBSTETRICS AND GYNECOLOGY

TEACHING AWARDS:

1997	CREOG National Faculty Resident Teaching Award
1993	APGO Excellence in Undergraduate Medical Education Award

MEDICAL ADVISORY BOARDS:

1993 - 1995	EMPI, Inc. St. Paul, Minnesota
1997 - 1999	EmpowerMed Yardley, Pennsylvania
2001 – 2003	Medcases Philadelphia, Pennsylvania

MEMBERSHIP ACTIVITIES AND COMMITTEES:

Michael Reese Hospital and Medical Center

1987 - 1988	Chief Resident's Council
1987 - 1988	Residency Evaluation Committee
1988	Hospital Utilization Review Committee

Harbor-UCLA Medical Center

1989 - 1991	Surgical Case Review Committee.

University of Illinois at Chicago, College of Medicine

1991 - 1993	Committee on Hospital Infections
1991 - 1997	OB/GYN Department Quality Assurance Committee
1991 - 1993	Medical Staff Quality Assurance Committee
1993	Ad Hoc Pap Smear Task Force
1993	Ad Hoc Committee to Review the 5 Year Deceleration Medical Student Program
1995 - 1997	Medical Records Committee
1996 - 1997	Generalist Curriculum Subcommittee
1997	Committee to Review the Performance of the Head of the Department of Urology

GRANTS AND CONTRACTS:

1989 - 1990	#PQ 1402-02B Investigator "A Randomized, Controlled, Comparative Clinical Trial of Thiamphenicol Glycinate/Thiamphenicol Versus Cefoxitin/Doxycycline in the Treatment of Pelvic Inflammatory Disease." Sponsor: *Pharmaquest Corporation*
1989 - 1991	#35614-87 Investigator "A Randomized, Open-Label, Comparative, Multicenter, Safety, Tolerance and Efficacy Study of Parenteral Pip eracil I in/Tazobactam (CL 298.741) versus Clindamycin Plus Gentarnicin in the Treatment of Hospitalized Patients with Gynecologic Infections." Sponsor: *American Cyanamid*
1990 - 1991	#MDS 401-US Investigator "Micturin versus Placebo in the Treatment of Urge Incontinence in Females. " Sponsor: *Forest Laboratories*
1992 - 1993	#C91-002 Principal Investigator "A Six Month Evaluation of Efficacy, Safety and Tolerance of the Lea's Shield. A Vaginal Barrier Contraceptive Device." Sponsor: *Contraceptive Research and Development Program*
1995 - 1997	#1393-027Principal Investigator "Phase II Safety and Efficacy Study of Fem Cap Used With and Without Spermicide. " Sponsor: *Contraceptive Research and Development Program*

INVENTIONS AND PATENTS:

1. Double Lumen Amnioinfusion Catheter. U.S. Patent Number 4,722,730, February 2, 1998. "Amcath". Manufactured by Gish Biomedical, Santa Ana, California.

2. "Meconium Aspirator Set." Manufactured by Gish Biomedical, Santa Ana, California.

VIDEO PRESENTATIONS:

Freedman A, Rosenzweig B, Maurice J., An Interesting Presentation of Failed Medical Termination with Hysteroscpic Resection of Retained Products of Conception. 41st Global Congress of minimally Invasive Gynecology Las Vegas, Nevada November 2012

MULTIMEDIA

FILM

1. *Design*. Feature Film. Premiere Sundance Film Festival January 2002.Co-Producer.
2. *Kwik-Stop.* Feature Film. Premiere Los Angeles Film Festival April 2001. Actor.
3. *The 95th*. Documentary. Premiere Maryland Film Festival May 2002. Co-Producer.
4. *Independent films and filmmakers*. Short Documentary. 1998. Producer, Director.

COMPUTER INTERACTIVE TEACHING PROGRAMS

Urogynecology: Evaluation and Treatment of Urinary Incontinence. CD Rom; Produced by Interactive Medical Review, Philadelphia, Pennsylvania, 1994.

MULTIMEDIA (Cont):

STREAMING MEDIA

1. Live Webcast of the First Streaming Media Conference. 1998. Producer, Director.

INDUSTRIAL VIDEO

1. *A Day at the Office*. WellSpring Management Group, Bethany, Connecticut. 1998. Producer, Director.
2. *Point of View Skiing*. American Ski Corporation, Sugarbush, Vermont. 1998. Producer.
3. *Promotional Video*. IMET Coporation, Philadelphia, Pennsylvania. 1999. Producer, Director.

PRESENTATIONS AND INVITED LECTURES:

Michael Reese Hospital and Medical Center

1 . "A Prospective Randomized Study Comparing Nipple Stimulation and Exogenous Oxytocin Contraction Stress Tests. " Presented at the First Annual Resident Research Conference, Michael Reese Hospital and Medical Center, Chicago, Illinois. June 11, 1987.

2. "Postpartum Uterine Inversion." Grand Rounds, Michael Reese Hospital and Medical Center, Chicago, Illinois. September 10, 1987.

3. Faculty Member: Basic and Advanced Laser Surgery, Hysteroscopy, Colposcopy, and Operative Laparoscopy, A "Hands-On" Course and Seminar, Washington, DC. January 25-28, 1989.

4. "Tubo-ovarian Abscess: Medical versus Surgical- Management." Grand Rounds, University of Nairobi, Nairobi, Kenya. March 2, 1989.

5. "HPV DNA and Squamous Atypia." Presented at the Tenth Annual Scientific Congress and Advanced Postgraduate Laser Course of the Gynecologic Laser Society, Orlando, Florida. March 31, 1989.

6. "Postpartum Uterine Inversion: Diagnosis and Management." Grand Rounds, SUNY-HSC, Syracuse, New York. March 17, 1989

7. Faculty Member: Basic and Advanced Laser Surgery: A Complete 5-Day "Hands-On" Course and Seminar, Virginia Beach, Virginia. July 24-28, 1989.

8. "HPV: The Disease of the 80's." Presented at the Los Angeles Regional Family Planning Council Family Planning Symposium, Torrance, California. January 20, 1990.

9. Faculty Member: Basic and Advanced Laser Surgery, Diagnostic and Operative Hysteroscopy, Advanced Colposcopy, Laser Laparoscopy, and Pelviscopy, A "Hands-On" Course and Seminar, Washington, DC. January 24-27, 1990.

10. "Office of Evaluation of Urinary Incontinence." Luncheon Conference at the Thirty-Eighth Annual Meeting of the American College of Obstetricians and Gynecologists, San Francisco, California. May 8, 1990.

11. Faculty Member: Basic and Advanced Laser Surgery, Diagnostic and Operative Hysteroscopy, Advanced Colposcopy, Laser Laparoscopy, Pelviscopy. A complete 5-Day 'Hands-On" Course and Seminar, Palm Beach, Florida. July 23-27, 1990.

12. "Lasers in Gynecology." Grand Rounds, Martin Luther King, Jr./Drew Medical Center, Los Ancreles, California. September 27, 1990.

13. "Urinary Incontinence and Genital Prolapse." Grand Rounds, HarboriUCLA Medical Center, Torrance, California. October 15, 1990.

PRESENTATIONS AND INVITED LECTURES (Cont):

14. Course Director: Contraceptive Technology: Symposium on Managing the IUD Patient. Planned Parenthood of San Diego and Riverside Counties, San Diego, California. October 27, 1990.

15. "Lasers in Urogynecology." Grand Rounds, Martin Luther King, Jr./Drew Medical Center, Los Angeles, California. November 8, 1990.

16. Course Director: Contraception in the 90's, Managing the IUD Patient. Oklahoma State Department of Health Maternal and Child Health Services, Oklahoma City, Oklahoma. March 1, 1991.

17. "Office Evaluation of Urinary Incontinence." Grand Rounds, Michael Reese Hospital and Medical Center, Chicago, Illinois. April 4, 1991.

18. Urinary Incontinence and Genital Prolapse. " Grand Rounds, University of Illinois at Chicago, College of Medicine, Chicago, Illinois. April 8, 1991.

19. “Urinary Incontinence." Women's Healthcare Center, Torrance, California. April 25, 1991.

20. "Evaluation and Management of Urinary Incontinence." South Bay Perinatal Access Project, San Pedro, California. May 3, 1991.

21. "Office Evaluation of Incontinent Women." Luncheon Conference at the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, New Orleans, Louisiana. May 7, 1991.

22. "Surgical Choices for Incontinence. " Luncheon Conference at the Thirty-Ninth Annual Meeting of American College of Obstetricians and Gynecologists, New Orleans, louisiana. May 8, 1991.

23. AUGS Special Interest Session: "Gynecological Urology: Case Management in Urogynecology. At the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, New Orleans, Louisiana. May 8, 1991.

24. "Vulvar and Vaginal Diseases." Colposcopy Training Course, Torrance, California. May 30, 1991.

25. "Managing the IUD Patient." Grand Rounds, Glendale Adventist Hospital, Glendale, California. June 10, 1991.

26. Course Director: Managing the IUD Patient. Arizona Family Planning Council, Phoenix, Arizona. June 15, 1991.

27. "Basic Urogynecologic Instrumentation; Proper Evaluation and Differential Diagnosis of Stress Urinary Incontinence." Gynecologic and Endoscopic Surgery. A Complete 5-Day "Hands-On" Course and Seminar, Palm Beach, Florida. July 22, 1991.

28. "Evaluation and Management of Urinary Incontinence." At the Fourth Annual National Association of Womens' Health Professional Conference, Chicago, Illinois. October 17, 1991.

29. Course Coordinator: Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology: A Hands-On Seminar. "Evaluation of the Incontinent Patient; IUD Update; Nonsurgical Management of the Incontinence." Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology, Snowbird, Utah. March 11-14, 1992.

30. "Managing the IUD Patient." Grand Rounds, Jackson Park Hospital, Chicago, Illinois. March 19, 1992.

PRESENTATIONS AND INVITED LECTURES (Cont):

31. "Evaluation and Nonsurgical Management of the Incontinent Patient." Grand Rounds, Jackson Park Hospital, Chicago, Illinois. April 2 & 19, 1992.

32. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, and "Evaluation of the Incontinence Patient." Visiting Professor Lecture, Albert Einstein Hospital, Philadelphia, Pennsylvania. April 6, 1992.

33. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Michael Reese Hospital, Chicago, Illinois. April 7, 1992.

34. "Surgery in the Elderly. Female Urinary Incontinence: A Gynecologists Point of View." At the United States Section of the International College of Surgeons, Chicago, Illinois. April 10, 1992.

35. "Managing the IUD Patient." American College of -Nurse Midwives. Illinois Chapter Meeting. University of Illinois, College of Nursing, Chicago, Illinois. April 13, 1992.

36. "Contraceptive Choices in the 1990's." Postgraduate Course at the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Las Vegas, Nevada. April 28-29, 1992.

37. "IUD and Contraception." Grand Rounds, Mount Sinai Hospital and Medical Center, Chicago, Illinois. May 6, 1992.

38. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Cook County Hospital, Chicago, Illinois. May 11, 1992.

39. "Managing the IUD Patient." Grand Rounds, Ravenswood Hospital, Chicago, Illinois. May 21, 1992.

40. "Nonsurgical Management of Urinary Incontinence. Grand Rounds, Humana Hospital/Michael Reese and Medical Center, Chicago, Illinois. June 4, 1992.

41. "Urinary Dysfunction." Obstetrics and Gynecology Review Course, Chicago, Illinois. June 5, 1992.

42. "Surgical Management Stress Incontinence of Urine; Management of Operative Complications; Comparison of Techniques for Management of CIN. Advanced Gynecologic Surgery: A Complete 5-Day "Hands-On" Course and Seminar, Palm Beach, Florida. July 20-22, 1992.

43. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Cook County Hospital, Chicago, Illinois. July 27, 1992.

44. "Nonsurgical Approach to Female Incontinence." Grand Rounds, Alexian Brothers Medical Center, Elk Grove Village, Illinois. September 3, 1992.

45. Course Director: Update on Urogynecology. "Evaluation of the Incontinent Patient; Nonsurgical Management of Stress Urinary Incontinence." Update on Urogynecology, Philadelphia, Pennsylvania. September 21, 1992.

46. "Urinary Incontinence: It Doesn't Have to be Part of a Woman's Everyday Life." Virginia Baptist Hospital, Lynchburg, Virginia. October 13, 1992.

47. "Managing the IUD Patient. Grand Rounds, Hershey Medical Center, Hershey, Pennsylvania. October 21, 1992.

48. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, University of Illinois at Champaign, Champaign, Illinois. October 28, 1992.

PRESENTATIONS AND INVITED LECTURES (Cont):

49. "Evaluation and Management of Urologic Problems in Women. " Gynecological Update 1991, La Mesa, California. October 31, 1992.

50. "IUD Insertion/Removal and Model Practicurn. At the Annual Family Planning, Obstetrics and Gynecology Update for Florida Nurse Practitioners, Orlando, Florida. November 5, 1992.

51, "IUD's Revisited." At the Statewide Clinician's Meeting, Planned Parenthood Wisconsin, Milwaukee, Wisconsin. November 13, 1992.

52. "The Nonsurgical Management of Stress Urinary Incontinence." Grand Rounds, University Hospital of Cleveland, Cleveland, Ohio. November 18, 1992.

53. "The IUD: A Second Look." A Contraceptive Symposium and Practicum. San Bernadino County Department of Public Health. Womens' Health Section, San Bernadino, California. November 20, 1992.

54. "Managing the IUD Patient." Grand Rounds, Department of Family Practice, University of Illinois, Chicago, Illinois. December 2, 1992.

55. "Manauing the IUD Patient." Grand Rounds, West Pennsylvania Hospital, Pittsburgh, Pennsylvania. January 12, 1993.

56. "Repair of Pelvic Floor Dysfunction; Voiding Disorders and How to Manage Them." Advanced Gynecologic Surgery, Washington, D.C. January 27, 1993.

57. Course Director: Controversies in Gynecology. "Nonsurgical Management of Stress Urinary Incontinence; Genital Prolapse and Lower Urinary Tract Dysfunction Controversies in Gynecology, St. Petersburg, Florida. February 11-12, 1993.

58. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Saginaw General Hospital, Saginaw, Michigan. February 15, 1993.

59. "Managing the IUD Patient." Oklahoma State Department of Health Practitioners Annual Meeting, Oklahoma City, Oklahoma. March 11, 1993.

60. Course Director: Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology. "Genital Prolapse and Lower Urinary Tract Dysfunction; Physiotherapy in the Treatment of Lower Urinary Tract Dysfunction; Surgical Management of Stress Urinary Incontinence; The Role of IUD's in Contraception." Beaver Creek Colorado. March 17-20, 1993.

61. "Managing the IUD Patient." Grand Rounds, Waukesha Memorial Hospital, Waukesha, Wisconsin. March 23, 1993.

62. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Evanston Hospital, Evanston, Illinois. March 25, 1993.

63. "Evaluation of the Incontinent Patient." Grand Rounds, West Pennsylvania Hospital, Pittsburgh, Pennsylvania. March 29, 1993.

64. "Managing the IUD Patient." Grand Rounds, Forbes Metro Hospital, Pittsburgh, Pennsylvania. March 30, 1993.

65. "Incontinence Differential Diagnosis, History and Physical Exam; Pelvic Floor Neurology for the Gynecologist: EMG and Pudendal Conduction Latency; Other Cause of Incontinence." At Urogynecology 1993 State of the Art, Frisco, Colorado. April 2-3, 1992.

PRESENTATIONS AND INVITED LECTURES (Cont):

66. "Intrauterine Device: Insertion and Management." Sixteenth Annual Seminar in Womens' Health Care, Dallas, Texas. April 16, 1993.

67. "Contraceptive Choices for the 1990's and Beyond." The Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Washington, D.C. May 4-5, 1 993.

68. "Managing the IUD Patient." Grand Rounds, La Grange Hospital, La Grange, Illinois. May 17, 1993.

69. "Evaluation and Management of Urinary Incontinence." Grand Rounds, Mount Sinai Hospital, Miami, Florida. May 25, 1993.
70. "Contraceptive Update." At the Tenth Annual Medical Update, Pittsburgh, Pennsylvania. June 2, 1993.

71. "Treatment of Urinary Incontinence." Obstetrics and Gynecology Review Course, Chicago, Illinois. June 10, 1993.

72. "Open Urinary Stress Incontinence Procedures." St. Louis, Missouri. June 16, 1993.

73. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Baylor College of Medicine, Houston, Texas. June 30, 1993.

74. "Urodynamic Testing; Nonsurgical Management of Urinary Incontinence; Bladder Injury: How to Avoid, How to Manage." At Principles of Advanced Conventional and Endoscopic Surgery, Palm Beach, Florida. July 26, 1993.

75. "Evaluation, Diagnosis and Management of Urinary Stress Incontinence." The Gynecologic Surgical Techniques, Chicago, Illinois. August 19, 1993.

76. "Pelvic Anatomy and Placement of Sutures for Paravaginal Repair and Correction of Stress Incontinence." Demonstrated Using Human Cadaver, Chicago, Illinois. August 20, 1993.

77. Course Director: Practical Urogynecology. "Behavioral Management of Incontinence; Painful Voiding Syndrome; Behavioral and Physical Therapy for Urinary Incontinence." Cleveland, Ohio. August 27-38, 1993.

78. "Evaluation of the Incontinent Patient." Resident Lecture, East Carolina University, Greenville, North Carolina. September 22, 1993.

79. "Non-Hormonal Contraception." Grand Rounds, East Carolina University, Greenville, North Carolina, September 22, 1993.

80. "Gynecologic Disorders; Pregnancy Changes and General Surgical Problems During Pregnancy." Specialty Review in Surgical Critical Care, Chicago, Illinois, October 4, 1993.

81. "Managing the IUD Patient." Grand Rounds, George Baptist Medical Center, Atlanta, Georgia, October 12, 1993.

82. "Managing the IUD Patient." Grand Rounds, Reading, Pennsylvania. October 19, 1993.

83. "IUD Update: Clinical and Demographics Issues." Grand Rounds, Ohio State University, Columbus, Ohio. November 4, 1993.

84. "Update on Amnioinfusion." Grand Rounds, St. Francis Hospital, Blue Island, Illinois. November 16, 1993.
85. "Management of Urinary Stress Incontinence." St. Michael's Hospital, Toronto, Ontario, Canada. December6, 1993.

86. "IUD Update: Clinical and Demographic Issues." Grand Rounds, Jackson Memorial

Hospital, Miami, Florida. January 12, 1994.

PRESENTATIONS AND INVITED LECTURES (Cont):

87. "Urogynecology: Differential Diagnosis and Evaluation of Female Incontinence; Surgical Therapies for Stress Incontinence; Diagnosis and Treatment of Detrusor Instability; Diagnosis and Surgical Therapies for Stress Incontinence, Gynecologist." At Frontiers in Gynecology,

Steamboat Springs, Colorado. January 25-26, 1994.

88. "Genital Prolapse and Lower Urinary Tract Dysfunction." At the Fifth Annual Midwest Clinical Conference, Chicago Medical Society, Chicago, Illinois. February 11, 1994.

89. "Bacterial Vaginosis." Grand Rounds, Chicago Osteopathic Hospital, Chicago, Illinois. February 17, 1994.

90. "Gynecologic Problems in Surgery." At the Specialty Review in General Surgery, Chicago, Illinois. February 18, 1994.

91. "Female Urinary Incontinence: Anatomy Physiology, Definitions; Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral Syndrome, etc.; Diagnosis and Treatment of Pelvic Floor Disorders; Cystourethroscopy: Instrumentation and Technique; Ureteral Catherization - Indications, Risks, Benefits." At Modern Menopause and Urogynecology, San Francisco, California. March 11-13, 1994.

92. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Kaiser Bellflower, Bellflower, California. March 29, 1994.

93. "Female Urinary Incontinence: Anatomy, Physiology, Definitions; Office Evaluation and Advanced Urodynamic Testing; Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral Syndrome, etc., Nonsurgical Therapies for Stress Incontinence; Cystourethroscopy: Instrumentation and Technique; Ureter Catherization Indications, Risks, Benefits." At the Advanced Gynecologic Endoscopy with Urogynecology, Palm Springs, California. April 9-10, 1994.

94. "Intrauterine Device: Insertion and Management" at the 17th Annual Seminar in Womens' Health Care. Dallas, Texas. April 15, 1994.

95. "Surgical Management of Stress Urinary Incontinence." Grand Rounds, University of Illinois, Champaign, Illinois. April 15, 1994.

96. "Anatomy of Pelvic Floor Supporting System; Rational Anatomical Approach to Pelvic Floor Defects." At Advanced Laparoscopic Techniques, Chicago, Illinois. April 21, 1994.

97. "Managing the IUD Patient." Grand Rounds, University of Wisconsin, Milwaukee, Wisconsin. April 27, 1994.

98. "Contraceptive Choices." At the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. Orlando, Florida. May 10-11, 1994.

99. "Update on the IUD: New Friend or Old Danger." Grand Rounds, Harbor-UCLA Medical Center, Torrance, California. May 23, 1994.

100. "Contraception." At the Specialty Review in Obstetrics and Gynecology, Chicago, Illinois. May 24, 1994.

101. "Problem Management: IUD's. At the Twenty-Second Annual Conference for Nurse Practitioners in Reproductive Healthcare. Milwaukee, Wisconsin. June 10, 1994.

102. "Pelvic Floor Disorder." At the Obstetrics and Gynecology Review Course, Chicago, Illinois. June 15, 1994.

PRESENTATIONS AND INVITED LECTURES (Cont):

103. "Female Urinary Incontinence: Treatment by Electrostimulation." Grand Rounds, Hospital du Sacre-Coeur, Montreal, Canada. June 16, 1994.

104. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Sparrow Hospital, Lansing, Michigan. June 21, 1994.

105. "Major Pelvic Hemorrhage: The Safest and Best Methods for Control; Vaginal Cones and Electrical Stimulation to Manage Stress Incontinence; What To Do With The Patient Who Continues To Leak After Multiple Incontinence Surgeries." At Operative Gynecology, Palm Beach, Florida. July 18-20, 1994.

106. "Repair of Genital Prolapse." Grand Rounds, Michael Reese Hospital, Chicago, Illinois. August 17, 1994.

107. "Evaluation, Diagnosis and Management of Urinary Stress Incontinence, Including Cystoscopy; Pelvic Anatomy and Placement of Sutures for Paravaginal Repair, Sacrospinous Fixation, and Connection of Stress Incontinence." At Gynecologic Surgical Techniques, Chicago, Illinois. August 18-19, 1994.

108. "Gynecologic Problems in Surgery; Surgery in Pregnant Women." At Specialty Review in General Surgery, Part I, Chicago, Illinois. August 22, 1994.

109. "Managing the IUD Patient." Grand Rounds, Medical College of Wisconsin, Milwaukee, Wisconsin. August 25, 1994.

110. "Managing the IUD Patient." Grand Rounds, Rush University, Chicago, Illinois. September 8, 1994.

111. "Gynecologic Problems in Surgery." At Specialty Review in General Surgery, Chicago, Illinois. September 19, 1994

112. "IUD Symposium." At the Colorado Department of Public Health, Womens' Health Symposium, Silverthorne, Colorado. October 5, 1994.

113. "Urinary Incontinence." Grand Rounds, St. Elizabeth Hospital, Chicago, Illinois. October 18, 1994.

114. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Christ Hospital, Oak Lawn, Illinois. October 24, 1994.

115. "Evaluation of Urinary Incontinence and the Bladder Neck Suspension." Atlanta, Georgia. November 18, 1994.

116. "Managing the IUD Patient." Grand Rounds, Mount Sinai Hospital, Hartford, Connecticut. January 6, 1995.

117. "Managing the IUD Patient." At the New Mexico Department of Health Clinicians Seminar, Albuquerque, New Mexico. January 26, 1995.

118. "Gynecologic Problems in Surgery." At the Specialty Review in General Surgery, Chicago, Illinois. February 2, 1995.

119. "Urinary Incontinence in Women." At the Womens' Health Issues 1995, India Medical Association (IL), USA, Chicago, Illinois. March 12, 1995.

120. "Bacterial Vaginosis." Grand Rounds, Anchor HMO, Chicago, Illinois. March 28, 1995.

121. "Urinary Incontinence in Women: What's New." Metropolitan Chapter of the American

College of Surgeons Meeting, Chicago, Illinois. April 27, 1995.

PRESENTATIONS AND INVITED LECTURES (Cont):

122. "Evaluation of the Incontinent Patient; Surgical Management of SUI - Open Approach." at the Operative Laparoscopy, Hysterectomy, Pelvic Floor Repair and Hysteroscopy for Gynecologist. Atlanta, Georgia, June 16-17, 1995.

123. "Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral syndrome, etc; Cystrourethros copy - instrumentation and techniques; Urethral Catheterization indications, risk, benefits; abdominal procedures for GSI; non surgical therapy for GSI." at Advanced Gynecology Endoscopy and Uro-gynecology, Vancouver, Canada, August 19, 1995.

124. "Evaluation of the Incontinent Patient; Surgical Management of SUI - Open Approach." At the Operative Laparoscopy, Hysterectomy, Pelvic Floor Repair and Hysteroscopy for Gynecologist. Atlanta, Georgia, September 29-30, 1995.

125. "Managing the IUD Patient." At The Regional meeting of AMWA. Chicago, Illinois, September 23, 1995.

126. "The Evaluation of the Incontinent Patient and Bladder Neck Suspension." At the Operative Laparoscopy, Hysterectomy, Hysteroscopy and Pelvic Floor Repairs for gynecologists. Atlanta, Georgia, September 29-30, 1995.

127. "Manaaement of Severe Genital Prolapse. " Grand Rounds - University of Illinois Champaign, Illinois November 1, 1995.

128. "Pelvic Prolapse. " at the Obstetrics and Gynecology Tutorial - Oak Brook, Illinois, November 10, 1995.

129. "Algorithms for the Management Urinary Incontinence": A modern, systematic approach to Diagnosis and Treatment; Retropubic Operations for Stress Incontinence: Patient Selection, Techniques and Outcome; Cystovaginal and Rectovaginal Fistula Repair: Operations, Techniques and Outcomes. Operative Laparoscopy and Urogynecology Course, Steamboat Springs Colorado, February 7-9, 1996.

130. "Contraception" At the Osler Review Course, St. Louis, Missouri, April 21, 1996.

131. "Laparoscopic Bladder Neck Suspension; Vaginal Vault Suspension." at the Advanced Operative Endoscopy Course and Hysteroscopy Workshop, Palo Alto, California, June 1,1996.

132. "Contraceptive Update" Osler Review Course, Chicago, Illinois, June 18, 1996.

133. "Menstrual Disorders; Urinary Incontinence; Pelvic Pain; Menopausal Syndrome. " Osler Review Course, Lisle, Illinois, July 10, 1996.

134. "Anatomy of the Pelvic Floor and Physiology of Incontinence; Evaluation of Urinary Incontinence and Pelvic Floor Disorders and Open Procedures for Urinary Incontinence. Cincinnati, Ohio, July 26, 1996.

135. "Role of Endoscopy in Reconstructive Pelvic Surgery; Evaluation of Urinary Incontinence and Open Surgical Management of Urinary Incontinence." At the Operative Gynecologic Hysteroscopy and Laparoscopy course Atlanta, Georgia, September 6-7, 1996

136. "An Overview of Urinary Stress Incontinence. " At the American Association of Gynecologic Laparoscopists, Chicago, Illinois, September 27, 1996.

137. "Gynecologic Problems in Surgery." General Surgery Review Course, Chicago, Illinois, October 9, 1996.

138 "Contraception. " Chicago Area Review Course, Chicago, Illinois, October 16, 1996.

PRESENTATIONS AND INVITED LECTURES (Cont):

139. "Contraception. " Obstetrics and Gynecology Review, Chicago, Illinois, November 6,1996.

140. "Contraceptive Update." Grand Rounds, Michael Reese Hospital, Chicago, Illinois, January 9, 1997.

141. "Contraceptive Update." Chicago Obstetrics and Gynecology Review, Chicago, Illinois, April 16, 1997.

142. "Contraception; Ectopic Pregnancy; Injections and Antibiotics; HIV and the Woman Patient; Obstetrical Emergencies." At the Obstetrics and Gynecology Review Course, St. Louis Missouri, April 23, 1997.

143. "Urinary Incontinence." "Practical Pearls for Women's Health Care: A Clinical Perspective" At the University of Illinois at Chicago, Illinois, May 17, 1997.

144. "Urinary Incontinence: Evaluation and Open Surgical Repair; Role of Laparoscopy in Pelvic Reconstructive Surgery." At the Laparoscopic Pelvic Surgery Course, Atlanta Georgia, May 23-24, 1997.

145. "Painful Bladder Syndromes." At the 25' Annual Conference for Nurse Pratictioners in Women's Health, Milwaukee, Wisconsin, June 11, 1997.

146. "Contraception; Ectopic Pregnancy; Infections and Antibiotics." Arlington Heights, Illinois, June 25, 1997.

147. "Contraceptive Update." Springfield, Illinois, July 24, 1997.

148. "Evaluation and treatment of urinary incontinence; painful bladder syndromes: Interstitial cystitis, urethral syndrome, and sensory urgency; Treating pelvic floor dysfunction" at Advances in Health Care for Women Over 40. Jackson Hole, Wyoming, August 7-8, 1997.

PRESENTED ABSTRACTS:

1. Levy JS, Rosenzweig BA, Kaplan B, et al: Changed criteria for antenatal fetal heart rate testing: A five year single institution experience. Presented at the Eighth Annual Meeting of the Society of Perinatal Obstetricians, February 6, 1988, Las Vegas (Abstract #267).

2. Bergman F, Rotmensch S, Rosenzweig BA, et al: Analysis of Factor VIII complex and Von Willebrand factor multimers in preeclampsia. Presented at the Thirty-Sixth Annual Meeting of the Society for Gynecologic Investigation, March 17, 1989, San Diego (Abstract #277).

3. Thomas S, Karram M, Rosenzweig BA, Bhatia NN: Long-term experience with the Birch procedure: Effects of menopausal status on outcome. Presented at the Thirty-Eighth Annual Meeting of the American College of Obstetricians and Gynecologists, May 9, 1990, San Francisco.

4. Rosenzweig BA, Soffici AR, Thomas S, Bhatia NN: Voiding patterns of patients with cystocele. Presented at the Twelfth Annual Symposium of the Urodynamics Society, May 12, 1990, New Orleans.

5. Rosenzweig BA, Bhatia NN: The use of carbon dioxide laser in urology. Presented at the Eleventh Annual Meeting of the Gynecologic Laser Society, June 10, 1990, Chicago.

6. Roserizweig BA, Bhatia NN, Hischke D, et al: The psychological profiles of women before and after surgical treatment of stress urinary incontinence. Proceeding of the Twentieth

Annual Meeting of the International Continence Society, September 12-15, 1990, Aarhus, Denmark.

PRESENTED ABSTRACTS (Cont):

7. Rosenzweig BA, Bhatia NN: Temporal separation of urethral and bladder pressure spikes during cough in women with stress urinary incontinence, urge incontinence and after incontinence surgery. Proceeding of the Twentieth Annual Meeting of the International Continence Society, September 12-15, 1990, Aarhus, Denmark.

8. Rosenzweig BA, Bhatia NN, Hischke D, Thomas S, Nelson AL: The psychological status of women before and after treatment of stress incontinence. Presented at the Eleventh Annual Meeting of the American Uro-Gynecologic Society, November 1, 1990, Tarpon Springs.

9. Roserizweig BA, Bhatia NN, Nelson AL: Pressure transmission ratio: What do the numbers really mean? Presented at the Eleventh Annual Meeting of the American Uro-Gynecologic Society, November 2, 1990, Tarpon Springs.

10. Rosenzweig BA, Blumenfeld D, Bhatia NN: Incidence of urinary incontinence in asymptomatic women with severe genitourinary prolapse: A rationale for preoperative urodynamic evaluation. Presented at the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, May 7, 1991, New Orleans.

11. Rosenzweig BA, Blumenfeld D, Bhatia NN: Pessary test in the evaluation of detrusor instability in women with genitourinary prolapse. Proceeding of the Twenty-First Annual Meeting of the International Continence Society, October 10-12, 1991, Hannover, Germany.

12. Rosenzweig BA, Blumenfeld D, Bhatia NN: Detrusor instability in women with genitourinary prolapse: Correlation of pessary test with operative results. Presented at the Twelfth Annual Meeting of the American Uro-Gynecologic Society, October 23, 1991, Newport Beach

13. Rosenzweig, BA, Bhatia NN, Karram. MM, Blumenfeld D: Management. of recurrent severe stress urinary incontinence using modified suburethral sling procedure: Autologous versus synthetic material. Presented at the Twelfth Annual Meeting of the American Uro Gynecologic Society, October 25, 1991, Newport Beach.

14. Rosenzweig BA, Prins GS, Bolina PS, et al: Steroid receptors of the lower urinary tract in the rabbit. Presented at the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. May 5, 1993. Washington, DC.

15. Rosenzweig BA, Scotti RJ: The state of resident education in urogynecology. Presented at the CREOG and APGO Annual Meeting. March 2-5, 1994, Nashville.

16. Hopkins S, Rosenzweig B, Maurice J. Laparoscopic Retrieval of an Intraperitoneal Intrauterine Devic. 42nd Global Conference of Minimally Invasive Gynecology. November 2013. Washingon DC.

PUBLICATIONS:

BOOK CHAPTERS:

1. Gunning JE, Rosenzweig BA. Evolution of endoscopic surgery. In: White RA, Klein SR, eds. *Endoscopic Surgery*. St. Louis, Mosby-Yearbook, Inc., 1991:3.

2. Bhatia NN, Rosenzweig, BA. The urologically oriented neurological examination. In: Ostergard DR, Bent AE, eds. *Urogynecology and Urodynamics: Theory and Practice*,

3rd ed. Baltimore, Williams and Wilkins, 1991:102.

3. Rosenzweig BA. Endoscopy evaluation of the lower urinary tract. In: Walters MD, Karram MM, eds. *Clinical Urogynecology*. St. Louis, Mosby-Yearbook, Inc., 1993:124.

4. Rosenzweig BA. Radiologic studies of the lower urinary tract. In: Walters MD, Karram MM, eds. *Clinical Urogynecology*. St. Louis, Mosby-Yearbook, Inc., 1993:134.

BOOK CHAPTERS (Cont):

5. Lind LR, Rosenzweig BA, Bhatia NN. Urologically oriented neurological examination. In Ostergard Dr. Bent AE, eds. *Urogynecology and Urodynamics: Theory and Practice 4th ed*., Baltimore, Williams and Wilkins, 1996:99.

6. Maurice JM, Rosenzweig BA. Acute Female Pelvic Pain *Common Surgical Diseases: An Algorithmic Approach, 3rd Edition,* In Press

LETTERS TO THE EDITOR:

1. Levy J, Rosenzweig BA, Blumenthal P: Amnioinfusion for fetal distress. *Am J Obstet Gynecol*, 1986;155:1361.

2. Levy J, Rosenzweig BA: Intubation and resuscitation of meconium-stained newborns. *Resp Care*, 1987;32:130.

3. Levy J, Rosenzweig BA, Blumenthal P: Comparison of uterine activity by nipple stimulation and oxytocin. *Obstet Gynecol*, 1987;70:430.

4. Blumenthal P, Rosenzweig BA: The prophylactic effect of doxycycline on postoperative infection rate after first-trimester abortion. *Obstet Gynecol*, 1988;72:146.

5. Rosenzweig BA: Dynamic urethral pressure profilometry pressure transmission ratio: What do the numbers really mean? Letter (in reply). *Obstet Gynecol*, 1991;78:476.

PUBLISHED ABSTRACTS:

1. Rosenzweig BA, Rader JS, Padleckas R, et al: Correlation of human papillornavirus DNA and presence of atypical squamous cells in Pap smears. *Gynecol Oncol*, 1989;32:115.

2. Rosenzweig BA, Soffici AR, Thomas S, Bhatia NN: Voiding patterns of patients with cystocele. *Neurourol Urodynam*, 1990;9:230.

ORIGINAL ARTICLES:

1. Rosenzweig BA, Rotmensch S, Ressetar A: Term interstitial pregnancy resulting in a live infant. *Obstet Gynecol*, 1988;72:491.

*2. Blumenthal PD, Rosenzweig BA, Levy JS, et al: Ectopic pregnancy prevalence at a tertiary urban obstetrical center: The roles of previous surgery, hospital self-selection and detection bias. *Am J Gynecol Health*, 1988;2:18.

3. Levy JS, Rosenzweig BA, Blumenthal L: Bilateral tubal pregnancies after tubal sterilization. *Obstet Gynecol*, 1988;72:494.

*4. Rosenzweig BA, Rotmensch S, Binette SP, Philippe M: Primary idiopathic polymyositis and dermatomyositis complicating pregnancy: Diagnosis and management. *Obstet Gynecol Surv*, 1989;34:950.

5. Rosenzweig BA, Levy JS, Schipiour P, Blumenthal PD: Comparison of the nipple stimulation and exogenous oxytocin contraction stress tests: A randomized prospective study. *J Reprod Med*, 1989;34:950.

6. Rotmensch S, Rosenzweig BA, Philippe M: The impact of the AIDS epidemic on the philosophy of childbirth. *Am J Obstet Gynecol*, 1989; 161:855.

*** Non peer review**

ORIGINAL ARTICLES (Cont):

7. Rosenzweig BA, Seifer DB, Grand WD, et al: Urologic~ injury during vaginal hysterectomy. A case-control study. *J Gynecol Surg*, 1990;6:27.

*8. Rosenzweig BA, Birenbaum DL, Baggish MS: Pelvic inflammatory disease as a complication of carbon dioxide laser surgery of the cervix. *J Gynecol Surg*, 1989;5:117.

9. Baggish MS, Sze EHM, Rosenzweig BA, et a]: Direct hysteroscopic observation to document the reasons for abnormal bleeding secondary to submucous myoma. *J Gynecol Surg*, 1989;5:149.

10. Roserizweig BA, Baggish MS, Sze EHM: Carbon dioxide laser therapy for benign cervical tumors. *J Gynecol Surg*, 1990;6:97.

11. Sze EHM, Rosenzweig BA, Osborne NG, Baggish MS: Catheter-associated bacteriuria following gynecologic surgery. *J Gynecol Surg*, 1989;5:171.

12. Sze EHM, Rosenzweig BA, Birenbaum DL, et al: Excisional conization of the cervix uteri: A five-part review. Parts I and II. *J Gynecol Surg*, 1989;5:235.

13. Sze EHM, Rosenzweig BA, Birenbaum DL, et a]: Excisional conization of the uteri: A five part review. Parts III, IV and V. *J Gynecol Surg*, 1989;5:325.

14. Cohn GM, Rosenzweig BA, Adelson MD, Sze EHM: A complication associated with pneumatic compression stocking used for gynecologic surgery. *J Gynecol Surg*, 1989;5:389.

15. Rader JS, Rosenzweig BA, Spirtas R, et al: Atypical squamous cells: A case-series study of the association between Papanicolaou smear and human papillomavirus DNA genotype. *J ReprodMed*, 1991;36:291.

16. Bergman F, Rotmensch S, Rosenzweig BA, et al: The role of von Willebrand factor in preeclampsia. *Thromb Haemostas*, 1991;66:525.

17. Rosenzweig BA, Soffici AR, Thomas S, Bhatia N: Urodynamic evaluation of voiding in women with cystocele. *J Reprod Med*, 1992;37:162.

18. Rosenzweig BA, Bhatia NN: The use of carbon dioxide laser in female urology. *J Gynecol Surg*, 1991;7:11.

19. Rosenzweig BA, Hischke D, Thomas S, et al: Stress incontinence in women: Psychological status before and after treatment. *J Reprod Med*, 199 1;36:835.

20. Rosenzweig BA, Bhatia NN: Temporal separation of cough-induced urethral and bladder pressure spikes in women with urinary incontinence. *Urology*, 1992;39:165.

21. Karrarn MM, Rosenzweig BA, Bhatia NN: Artificial urinary sphincter for recurrent-severe stress urinary incontinence in women: Urogynecologic perspective. *J Reprod Med*, 1993;38:791.

22. Rosenzweig BA, Bhatia NN, Nelson AL: Dynamic urethral pressure profilometry pressure transmission ratio: What do the numbers really mean? *Obstet Gynecol*, 1991;77:586.

23. Rosenzweig BA: Neurological control of micturition. *J Gynecol Surg*, 1992;8:59.

24. Ogundipe A, Rosenzweig BA, Karrarn MM, et al: Modified suburethral sling procedure for the treatment of recurrent or severe stress urinary incontinence. *Surg Gynecol Obstet*, 1992;175:173.

*** Non peer review**

ORIGINAL ARTICLES (Cont):

25. Rosenzweig BA, Pushkin S, Blumenfeld D, Bhatia NN: Prevalence of abnormal urodynamic test results in continent women with severe genitourinary prolapse*. Obstet Gynecol*, 1992;79:539.

26. Rosenzweig BA: Genitourinary prolapse and lower urinary tract dysfunction. Int *Urogynecol J*, 1993;4:296.

27. Regan MA, Rosenzweig BA: Vulvar carcinoma in pregnancy: A case report and literature review. *Am J Perinatal*, 1993;10:334.

28. Font GE, Brill Al, Stuhldreher PV, Rosenzweig BA: Endoscopic management of incidental cystotomy during operative laparoscopy*. J Urol*, 1993;149:1130.

*29. Marcovici I, Rosenzweig BA, Brill Al, Khan M, Scommegna A: Cervical pregnancy: Case reports and a current literature review. Obstet Gynecol Surv, 1994;49:49.

30. Norton P, Karram M, Wall LL, Rosenzweig BA, et al: Randomized double-blind trial of terodiline in the treatment of urge incontinence in women. *Obstet Gynecol*, 1994;84:386

31. Marcovici I, Rosenzweiiz BA, Brill Al, Scommegna A: Colchicine and post inflammatory adhesions in a rabbit model: A dose response study. *Obstet Gynecol*, 1993;82:216.

32. Baggish, MS, Brill Al, Rosenzweig BA, et al: Fatal acute glycine and sorbitol toxicity during operative hysteroscopy*. J Gynecol Surg*, 1993;9:137.

33. Rosenzweig BA, Bolina PS, Birch L, et al: Location and concentration of estrogen, androgen, and progesterone, and androgen receptors. in the bladder and urethra of the rabbit. *Neurourol Urodynam*, 1995;14:87.

34. Rosenzweig BA, Even AH, Scotti RJ: The state of resident education in urocrynecology. *Int Urogynecol J*, 1995;6:18.

35. Rosenzweig BA, Brill Al: Laparoscopic colposuspension operation, Pro. J Gynecol Surg*, 1994;10:203.

36. Rosenzweig BA: Severe genital prolapse and its relationship to detrusor instability. *Int Urogynecol J*, 1995; 6:86.

37. Mauck C, Glover L.H., Miller E, Allen S, Archer DF, Blumenthal P, Rosenzweig BA et al: Lea's Shield: A phase 1 study of the safety and efficacy of a new vaginal barrier contraceptive used with and without spermicide. *Contraception,* 1996; 53:329.

38. Rosenzweig BA, Even A, Budnick LE: Observations of scanning electron microscopy detected abnormalities of untreated latex condoms. *Contraception*, 1996; 53:49.

*** Non peer review**

Revised: August 5, 2013

March 4, 2014

To Whom It May Concern:

From: Bruce A. Rosenzweig, M.D.

Please note the following fees for expert opinion $750.00 per hour for review of medical records and conference, $1,500.00 per hour for deposition, and $10,000.00 for trial testimony plus travel and hotel expenses. Please forward a **retainer amount of $15,000.00** payable to Dr. Bruce Rosenzweig to be sent with medical records (Tax ID# 201637125). Payment may be mailed to the address listed. Should you have any questions please call the office.

Sincerely,
/Bruce Rosenzweig/
Bruce A. Rosenzweig, M.D.

Exhibit B

Testimonial History
of
Bruce Alan Rosenzweig, M.D.
2009 to Present

Donald Budke v. Becky Simpson, M.D.
Court Case No. 10CM-CC00085
Missouri Circuit Court, 26th Judicial Circuit

Roxann Comried v. Thomas Getta, M.D., *et al.*
Court Case No. LA CV062272
Linn County District, Cedar Rapids, IA

Mary Ann Grady v. Jorge Romero, M.D.
Court Case No. CV-2011-10-5610
Ohio Common Pleas Court, Summit County, OH

Beverly Green v. Fitzgibbon Hospital
Court Case No. 08SA-CV00057
Missouri Circuit Court, 15th Judicial Circuit

Sandra L. Greene v. Lia D. Shorter, M.D., *et al.*
Court Case No. CL10000246-00
Fredericksburg Circuit Court, Fredericksburg, VA

Brooke Hollan v. Daniel Gehlbach, M.D.
Court Case No. 09CV02184
Johnson County District Court, KS

Tammy Jefferson, *et al.* v. Greater Washington Medicenter, LLC
Court Case No. CAL09-15527
Circuit for Prince George's County, MD

Mary King v. Michael Heit, M.D.
Court Case No. 13-CI-003843
Jefferson County, KY

Mary Labbe v. Summa Hospital System
Court Case No. CV-2010-11-7805
Ohio Common Pleas Court, Summit County, OH

Christy McKinney v. Summa Health System
Court Case No. CV-2011-10-5843
Ohio Common Pleas Court, Summit County, OH

Melissa Mills v. Parag Patel, M.D.
Court Case No. 05-CI-02315
Circuit Court, Boone County, KY

Judith Nash v. Kianoush Khaghany, *et al.*
Court Case No. Unknown
Michigan Circuit Court, 38th Judicial Circuit, MI

Deborah O'Donnell v. Antoinette Berkley, M.D.
Court Case No. 000971/2007
Supreme Court of New York, 9th Judicial District NY

Patricia Pater v. Mercy Health System
Court Case No. 10LA000347
Illinois Circuit Court, 22nd Judicial Circuit, IL

Marilyn Pitton, *et al.* v. Kim Josen, M.D., *et al.*
Court Case No. CV2010-050204
Arizona Superior Court, Maricopa County, AZ

Marie Skelnik v. Donald C. Whiteside, M.D.
Court Case No. 08-CVS-3683
Superior Court, Mecklenburg County, IL

Mason Smith v. John Payne, M.D.
Court Case No. 49D04-0511-CT-42869
Marion County Superior, Indianapolis, IN

Noshay v. Northwestern Medical Center
Court Case No. 10 L 004822
Cook County, IL

Tara Mills v. Todd P. Berner, M.D.
Court Case No. Unknown
Virginia

Christine A. Warner v. Thomas W. Hinz
Court Case No. Unknown
Georgia

Barbara Duckworth v. American Medical Systems
Court Case No. 201137645
Texas District Court, Harris County, TX

Lewis v. Ethicon (TVT)
Case # 2: 12 - CV – 04301
U. S. District Court Southern District of West Virginia
Deposition 11/01/2013

Elizabeth Guiterrez v Westlake Hospital et. al
Court No. 09 L 4276
Case No. 2010013165 (Illinois either Cook or Du Page county)
Deposition 11/21/2013

Lewis v Ethicon (TVT)
Case # 2: 12 - CV – 04301
U. S. District Court Southern District of West Virginia
Trial 02/11/2014

Huskey v. Ethicon (TVT-O)
Case # 2: 12 – CV – 09972
U. S. District Court Southern District of West Virginia
Deposition 3/25/14

Martinez v AMS and Endo Pharmaceuticals (Elevate & MiniArc)
Cause No. DC-13-13098
District Court of Harris County, Texas
Deposition 3/31/2014

Blankenship & Pugh v Boston Scientific Corp (Obtryx)
Case No. 2:13-cv-22906 and 01565
U. S. District Court Southern District of West Virginia
Deposition 6/09/2014

Stamper v The Christ Hospital et al
Case No. A 1205079
Hamilton County, Ohio
Deposition 6/18/2014

Carter v Glazerman, Tampa General Hosp
Case No.: 12-CA-009942
Hillsborough County, Florida
Deposition 7/03/2014

Huskey v Ethicon (TVT-O)
Case #2: 12 –CV – 09972
U. S. District Court Southern District of West Virginia
Trial Testimony 8/25-26/2014

Corbet v Ethicon (TVT-R)
Case #291
Docket No. ATL-L-2911-13
Superior Court of New Jersey, Atlantic County
Deposition 8/29/2014

Ramirez v Ethicon (TVT-O)
Civil Action # 2012-CI-18690
District Court 438th Judicial District, Bexar County, Texas
Deposition 10/11/2014

MDL v CR Bard (Align)
MDL No. 2187
U. S. District Court Southern District of West Virginia
Deposition 10/29/2014

Covington et al v CR Bard
MDL No 2187
Case # 2:12 cv-05114
U. S. District Court Southern District of West Virginia
Deposition 10/30/2014

Green et al v CR Bard
MDL No 2187
Case # 2:13 cv-30766
U. S. District Court Southern District of West Virginia
Deposition 10/31/2014

Tyree et al v Boston Scientific Corp (Obtryx)
MDL No 2326
Case # 2:12 cv – 08633
U. S. District Court Southern District of West Virginia
Trial Testimony 11/4/2014

MDL v Boston Scientific Corp (Advantage/Lynx)
MDL No 2325 – Advantage
U. S. District Court Southern District of West Virginia
Deposition 11/24/2014

Brock et al v CR Bard
MDL No 2187
Case # 2:12-cv-05114
U. S. District Court Southern District of West Virginia
Deposition 11/29/2014

Carlson et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-5475
U. S. District Court Southern District of West Virginia
Deposition 12/01/2014

Higginbotham et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-5475
U. S. District Court Southern District of West Virginia
Deposition 12/03/2014

Craft et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-04433
U. S. District Court Southern District of West Virginia
Deposition 12/08/2014

Collins et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-11658
U. S. District Court Southern District of West Virginia
Deposition 12/10/2014

Perry v Ethicon (Abbrevo)
Case No.: 1500-cv-279123 LHB
Superior Court of the State of California
County of Kern
Deposition 12/15/2014

Spohn et al v CR Bard
MDL No 2187
Case # 2:13 cv-30512
U. S. District Court Southern District of West Virginia
Deposition 12/18/2014

Perry v Ethicon (Abbrevo)
Case No.: 1500-cv-279123 LHB
Superior Court of the State of California
County of Kern
Trial Testimony 01/29/2015, 02/02/2015, 02/03/2015

Pantoja & Porter v CR Bard
MDL No 2187
Case # 2:14 cv-01353
U. S. District Court Southern District of West Virginia
Deposition 02/09/2015

Kerrn v Wagner
Case No.: 13-CA-009513
Circuit Court of the Thirteenth Judicial Circuit Hillsborough County, Florida
Civil Division
Deposition 04/02/2015

Acosta et al v CR Bard
MDL No 2187
Case # 2:13 cv-06855
U. S. District Court Southern District of West Virginia
Deposition 05/11/2015

Colletti et al v CR Bard
MDL No 2187
Case # 2:14 cv-11534
U. S. District Court Southern District of West Virginia
Deposition 05/18/2015

Brenner et al v Mentor (Obtape)
MDL Case No. 2004
U. S. District Court Middle District of Georgia
Colombus Division
Deposition 07/09/2015

Cavness v Ethicon (Prosima)
Cause No. DC-14-04220
95th District Court
Dallas County, Texas
Deposition 07/13/2015

Sherrer v Boston Scientific and CR Bard (Align & Solyx)
Case No. 1216-CV27879 Division 15
Circuit Court of Jackson County, Missouri at Kansas City
Deposition 8/3/2015

Kilgore v American Medical Systems (Elevate)
Case No.:14CV01312 Division: 14
District Court of Johnson County Kansas
Civil Court Department
Deposition 8/12/2015

Suen et al v Mentor (Obtape)
MDL Case No. 2004
U. S. District Court Middle District of Georgia
Colombus Division
Deposition 09/10/2015

Cantrell v Ethicon (TVT-R)
Master Docket No. Ber-L-11575-14
Superior Court of New Jersey Law Division – Bergen County
Deposition 09/16/2015

Mullins et al v Ethicon (TVT-R Design Defect)
MDL Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 09/22/2015

Cavness v Ethicon (Prosima)
Cause No. DC-14-04220
95th District Court
Dallas County, Texas
Trial 09/24/2015

Carlson v Boston Scientific (Uphold)
MDL No 2326
U. S. District Court Southern District of West Virginia
U. S. District Court Western District of North Carolina
Trial 10/08/2015

Sherrer v Boston Scientific and CR Bard (Solyx and Align)
Case No. 1216-CV27879 Division 15
Circuit Court of Jackson County, Missouri at Kansas City
Trial 12/10-11/2015, 12/14-16/2015

Carlino v Ethicon (TVT R)
No. 03470
Court of Common Pleas
Philadelphia County, Pennsylvania
De Bene Esse Deposition 12/22/2015; 01/13–14/2016

Carter v AMS (Sparc & Perigee)
C.A. No N10C-05-209-PEL
Superior Court 0f the State of Delaware
Deposition 1/18/2016

McGee v Ethicon (TVT Secur)
No. 3483
Court of Common Pleas
Philadelphia County, Pennsylvania
Deposition 2/04/2016

Burkhart et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 3/10/2016

Forester et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 3/11/2016

Herrera-Nevarez et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 3/12/2016

Vignos-Ware et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 3/13/2016

Wroble et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 3/19/2016

Ramirez v Ethicon (TVT-O)
Civil Action # 2012-CI-18690
District Court 438th Judicial District, Bexar County, Texas
De Bene Deposition 3/31/2016

Childress et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 5/22/2016

Meyer et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 5/26/2016

Cooper et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 6/04/2016

Hernandez et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 6/05/2016

Mullins Consolidated (TVT-R)
Bennett et al v Ethicon
MDL Master File No. 2:12-MD-02952
U. S. District Court Southern District of West Virginia
Deposition 06/22/2016

Mullins Consolidated (TVT-R)
Gillum et al v Ethicon
MDL Master File No. 2:12-MD-02952
U. S. District Court Southern District of West Virginia
Deposition 06/25/2016

Mullins Consolidated (TVT-R)
Burgoyne et al v Ethicon
MDL Master File No. 2:12-MD-02952
U. S. District Court Southern District of West Virginia
Deposition 06/26/2016

Jasso v Ethicon (Prosima)
State of New Mexico, County of Bernalillo
Second Judicial District No. D-202 CV-2013-05744
Deposition 07/14/2016

Mullins Consolidated (TVT-R)
Tomblin et al v Ethicon
MDL Master File No. 2:12-MD-02952
U. S. District Court Southern District of West Virginia
Deposition 07/20/2016

Hill et al v Ethicon
MDL 2327
Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 8/25/2016

Smith v Ethicon (TVT-O)
Master Docket No. Ber-L-11575-14
Superior Court of New Jersey Law Division Bergen County
Docket No. Ber-L-16720-14 MCL
Deposition 8/31/2016

Flores v Boston Scientific (Solyx, Pinnacle, Uphold)
Civil Action No. MICV2012-02867
Commonwealth of Massachusetts
Middlesex, SS. Superior Court
Deposition 12/19/2016

Engleman v Ethicon (TVT-S)
March Term, 2014 No. 5384
Philadelphia County Court of Common Pleas
Trial Division
Deposition 01/12/2017

Fee Schedule

Document Review, IME & Expert Report	$750/hour
Deposition	$1,500/hour
Half Day of Trial	$5,000
Full Day of Trial	$10,000

Exhibit C

Materials Reviewed

Depositions of Parties

Shelby Anders (12/22/2016)

Medical & Billing Records

Female Pelvic Medicine and Reconstructive Surgery
Horace E. Walpol Jr. M.D.
Jeffrey B. Garris, M.D.
Carolina Continence Center
Greenville Health System
Highlands Center for Women
Powdersville Internal Medicine
University Medical Group Department of OB/GYN Urogynecology Department
Greenville Hospital System
Oaktree Medical Centre, P.C.
Pathology Consultants, Inc.
Gastroenterology Associates, P.A.-Eastside Office
Brio Internal Medicine
ATI Physical Therapy
Carolina Orthopaedic Center
Carolina Cardiology Consultants, P.A.
LabCorp of America
Thomas F. Mattox, M.D.

Instructions for Use

Gynecare TVT-S Instructions for Use
Gynecare TVT-S Patient Brochures
Gynecare Prolift Instructions for Use
Gynecare Prolift Patient Brochures

Other

Plaintiff Fact Sheet
Plaintiff Profile Form
Defendants' Fact Sheet

Incorporated Materials

All materials cited in and reviewed for the TVT-S and Prolift general causation reports